IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., ROCHESTER DRUG CO-OPERATIVE, INC., MEIJER, INC., MEIJER DISTRIBUTION, INC., AMERICAN SALES COMPANY, LLC, WALGREEN CO., SAFEWAY INC., SUPERVALU INC., and HEB GROCERY CO. LP, et al.,	:	
Plaintiffs,	:	**Civ. No. 12-3824 CONSOLIDATED**
v.	:	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,	:	
Defendants.	:	

DEFENDANT WARNER CHILCOTT'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT AS TO ALL PLAINTIFFS' CLAIMS

PUBLIC REDACTED VERSION

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Plaintiffs' claims depend on establishing that Defendants' actions in introducing new Doryx products prevented Mylan from developing generic forms of Doryx. Plaintiffs recite various words of exclusion, *e.g.*, "foreclosed" (Mylan Opp. at 1), "block[ed]" (*id.* at 6), "exclusion of competitors" (*id.* at 11), "exclusionary conduct" (IPP Opp. at 5), and "prevent generic entry" (*id.* at 5). But—as Plaintiffs' experts have testified—no Section 2 exclusionary practices are present here: no exclusive contracts locking up the market, tying, fraud on the Patent Office, sham patent litigation, or predatory pricing.

It is fatal to Plaintiffs' claims that Mylan sat on its hands and did nothing to develop generic Doryx for so long. As its own witnesses admit, Mylan waited [redacted] years after the unpatented Doryx capsule was launched in 1985 to ***begin*** work on a generic form of Doryx in [redacted]. Kirsch Decl. ¶2, Nelson Reb. Rep. Ex. 61 (Ex. 108); *see* Appendix 18. Mylan's failure to "keep pace with" the Defendants (Mylan Compl. ¶71) stems from the [redacted]-year lead Mylan gave to the scientists at Mayne and Warner Chilcott. Eight Mylan witnesses—Workman, Mauro, Addicks, Kirsch, Korman, Bresch, Deiriggi, and Cestra—testified that Mylan, the far larger company, [redacted]. *See* Section III(A) below. Mr. Addicks put it bluntly: Mylan [redacted]. WC Opp. at 53. There is no generic "exclusion," as in cases like *Valley Drug*. *See* Mylan Opp. at 12.

Thus, this lawsuit boils down to whether the Sherman Act should be read nearly 125 years after enactment to impose a mandatory, positive duty on a manufacturer to continue selling indefinitely its older products, solely for the benefit of its competitors. Mylan is explicit that its theory of illegality has collapsed to Defendants simply introducing new drugs and withdrawing old drugs: "[t]he challenged conduct—strategic introduction and withdrawals of trivially

modified products." Mylan Opp. at 46. But the facts of this case do not justify creating a duty for a company to market a product for the sake of a competitor. The antitrust laws protect "competition, not competitors." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977).

Even if Plaintiffs' affirmative, anti-innovation duty to sell older products to help slow-moving competitors were adopted, Mylan's claims still should be dismissed now. That is because the undisputed evidence confirms that Mylan could not even have benefited from the creation of this novel duty. Even if a new duty were fashioned (and retroactively applied to business decisions made many years ago) to force Warner Chilcott to continue selling old Doryx capsules until a generic version were approved, ***Mylan would not have been the generic to benefit from that duty***. A different generic competitor, Sandoz, obtained FDA approval to launch a generic Doryx capsule first, in December 2005.[1] And according to Mylan's own Complaint, branded Doryx capsules were sold until June 2006 (Mylan Compl. ¶43), fulfilling any such novel duty as to the first generic (Sandoz). Mylan—even based on its own speculative, hypothetical claims—could not have launched a generic Doryx capsule until [redacted], almost [redacted] years after the first generic version of Doryx was approved.[2] Thus, Mylan admits it would have been some [redacted] years late to the game, well after the first generic competitor would have relieved Warner Chilcott of the duty to sell old Doryx versions.

Mylan's Self-Centered Rule of Reason Approach Is Devoid of a Test for What Constitutes the Requisite Anticompetitive Conduct in an Innovation Case.

Plaintiffs urge that a rule of reason analysis somehow be applied to Doryx, but they never come to grips with the fact that the first step in the analysis is establishing the existence of

[1] [redacted] SANDOZ-RDC-00009404 (Ex. 61); IPP Opp. at 3.

[2] [redacted], Nelson Reb. Rep. ¶4 (Mylan Ex. 226).

anticompetitive conduct. Mylan Opp. at 11–12 (citing to *Valley Drug* "exclusion"). Despite Defendants' earliest moving papers pressing for a test, Plaintiffs have never given the Court a test for anticompetitive conduct (or for what constitutes "illegitimate innovation"), and each of Plaintiffs' experts oddly but emphatically disavowed having any such test. WC Mem. at 12–15 (collecting testimony of plaintiffs' experts disavowing any test of innovation). The IPPs are silent on the issue entirely in their opposition.

Were a rule of reason test to be implemented as Plaintiffs urge, every new version of a drug would have to undergo an undefined rule of reason scrub—including some sort of weighing of safety, convenience, dosing flexibility, physician and patient preferences, and legitimate commercial concerns (*e.g.*, avoiding million dollar recalls). Plaintiffs' experts estimate that 65% to 85% of all new drugs in the United States are new versions of older drugs,[3] meaning that the Plaintiffs' rule of reason test profoundly would change and burden almost all pharmaceutical innovation in this country. We have had the rule of reason for 113 years (Mylan Opp. at 11), but no court has burdened pharmaceutical innovation with Mylan's amorphous and evolving wait-till-Mylan-is-ready test.

Discovery has proven that this is not the test case for imposing such burdens: Mylan's own economist Phil Nelson has not even analyzed all of the relevant Doryx drugs and potential benefits, including the most recent R&D successes in the Doryx franchise, the 200mg Doryx tablet, and a new chemical entity for acne—sarecycline ("novel tetracycline"). The FDA recently approved the 200mg Doryx tablet for a new once-a-day treatment for chlamydia, the

[3] Kesselheim Tr. 102:9–15 (Ex. 3) ("Q. So 85 percent of the new drugs in the period 1989 to 2000 did not contain new active ingredients and provide significant clinical improvement, correct? A. According to this study that was done, yes."); *see also Changing patterns of pharmaceutical innovation*, NIHCM Foundation 1–24 (2002); John A. Vernon & Robert Goldberg, Ctr. for Med. in the Pub. Interest, *Comparative Effectiveness Research: Effect on Pharmaceutical Innovation, Value of Health and Longevity* (2011).

most prevalent sexually transmitted disease in the United States.[4] Sarecycline is a potential breakthrough drug, funded by [redacted] of the profits and know-how from Doryx, and is in Phase III clinical trials.[5] Dr. Nelson, Mylan's lead economic expert, included neither product in his purported rule of reason weighing. Nelson Tr. 137:13–19 (Ex. 28) (admitting "I haven't done a thorough analysis of the 200 milligram"); *id.* 140:2–11 (Ex. 421) (admitting he has not weighed 200mg Doryx tablet in rule of reason analysis); *id.* 138:8–18 (admitting he has not "evaluated" sarecycline and has not "done an analysis" of it). Mylan tepidly claims that it needs more documents to evaluate sarecycline further (Mylan Opp. at 42), but Mylan did not pursue these topics in discovery, despite knowing about both from before this case began.

Plaintiffs' failure of proof with respect to their rule of reason analysis is inexcusable—Dr. Nelson knew about both the proposed 200mg Doryx tablet and sarecycline/novel tetracycline when he wrote his September 2011 expert report in the patent litigation (almost a year before this antitrust case was filed)[6]—and should prevent this case from going to any jury.

The Evidence Forced Plaintiffs to Jettison Several Claims.

Marketing and Detailing Claims Abandoned. Mylan's opposition claims exclusion from "switches" and uses flights of rhetoric such as "serial switches" (Mylan Opp. at 1) and "switched the market to 150mg tablets" (*id.* at 5–6)—always tied to an indictment of Defendants' promotional activities. For example, with respect to the Doryx 150mg tablet, it is undisputed that Warner Chilcott continued to sell the older versions of Doryx, the 75mg and 100 mg tablets, for years after the new 150mg tablets were launched. WC Opp. at 16; *see* Appendix 24. (This would satisfy even Plaintiffs' proposed duty to continue to sell older products.) But

[4] Kesselheim Tr. 79:20–80:21 (Ex. 3); *see also* Rubinfeld Tr. 289:2–20 (Ex. 390) (would be "troubling" if there are instances of morbidity, infant blindness, or infertility due to chlamydia).

[5] Boissonneault Tr. 430:4–16 (Ex. 255).

[6] Nelson Patent Decl. ¶¶43–44 (Ex. 395).

Mylan complains that 9 out of 10 doctors chose the newer version of Doryx over the older version. Plaintiffs challenged this "switching" of sales from old to new: "shifting approximately 90 percent of the prescriptions to the Doryx 150 mg Tablet . . . . through (1) the ***elimination of all promotional activities*** regarding the Doryx 75 mg and 100 mg Tablet Products." Mylan Compl. ¶62 (emphasis added).

However, faced with the binding Supreme Court precedent of *Sorrell* protecting drug company detailing under the First Amendment, and *Noerr-Pennington* immunity for petitioning, Mylan now announces in its opposition that drug promotion decisions, which were fundamental to the Mylan Complaint (*e.g.*, Compl. ¶¶5, 43, 44, 53, 62, 63), are now merely "incidental." Opp. at 45, 46, 46 n.59. Plaintiffs concede now that they do "not challenge advertising generally." Mylan Opp. at 15.

Citizen Petition Claims Abandoned. Mylan's opposition also announces (at 46–47) that Mylan no longer seeks to "impose liability for protected conduct"—such as FDA Citizen Petitions—thereby jettisoning several pages of the complaint. See Compl. ¶¶5, 50, 60, 67–71. Mylan's abandonment of these earlier gripes merely acknowledges the reality that as to the Citizen Petitions, the FDA agreed with Warner Chilcott, and not Mylan. Compl. ¶68. It is well-established that the Sherman Act is not a gap-filler for FDA regulatory advocacy disappointments. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 51 (1993) (successful petitioning immune).

March 1998 Licensing Agreement Challenge Abandoned. The March 1998 license agreement between Warner Chilcott and Mayne led to successful R&D of a new Doryx formulation and a more than 20-fold increase in Doryx output in the period from 1997 to 2005 alone. WC Opp. at 33, Table 2; *see* Appendices 20, 21. Plaintiffs' opposition bows to the

inevitable and declares: "The Doryx license agreement ***is not directly at issue*** except to the extent that it provides the ***backdrop*** against which other activities have occurred." Mylan Opp. at 45 (emphasis added).

Plaintiffs' Oppositions Ignore the Discovery in this Case.

Plaintiffs' 80 pages of opposition pay scant attention to the depositions taken in this case. Mylan's opposition cites to only two depositions of Mylan witnesses—Kirsch and Korman. The IPP opposition cites to ***none*** of the 100-plus depositions taken in this case. But the depositions here revealed many critical facts discussed throughout Defendants' summary judgment papers and warranting dismissal now, including: the absence of any blocking or exclusion of Mylan, [redacted],[7] the fact that Mylan's top selling EpiPen product employs the exact same legitimate strategy of discontinuing older versions of EpiPen in line extensions of new EpiPen products, and the fact that Mylan's generic Doryx often [redacted] than branded Doryx.

Plaintiffs' oppositions and the full discovery record confirm that Plaintiffs' claims fail in several additional ways:

- **No Standing and No Causation.** Plaintiffs lack standing, having suffered no cognizable antitrust injury. Moreover, Plaintiffs ignore clear Third Circuit authority (*e.g.*, *Ethypharm*) holding that a competitor cannot show causation where it abandons development without submitting an ANDA and chooses not to compete. WC Mem. at 44–50; WC Opp. at 50–61. Mylan's [redacted] years of inaction and voluntary choice to abandon capsules caused Plaintiffs' supposed injuries here, not Defendants.

- **No Duty to Help Competitors.** Defendants owed no duty to Mylan or any other putative manufacturer of generic Doryx under the antitrust laws. WC Mem. at 4–5; WC Opp. at 35–36.

- **Product Market: All Oral Tetracyclines.** Plaintiffs cannot prove a Doryx-only product market or that Defendants possessed monopoly power, leaving unrebutted Defendants' evidence showing interchangeability among a wide range of oral tetracycline products. WC Mem. at 21–36; WC Opp. at 62–65. Through Dr.

[7] Bresch Tr. 101:2–23 (Ex. 36) [redacted]

Rubinfeld's couponing chart, Plaintiffs admit that Warner Chilcott couponed heavily in the five years prior to the Mylan AB-rated generic, demonstrating the intense inter-brand rivalry between oral tetracycline products. *See* Appendix 16 at A41.

- **Ease of Entry Defeats Monopolization.** Plaintiffs' oppositions have no answer to the more than 40 oral tetracycline products that the FDA has approved since 2005. WC SJ Mem. at 34 & Appendix 5. Third Circuit law in *Barr Laboratories* makes ease of entry proof of a competitive market. Tellingly, of the 44 new oral tetracyclines the FDA has approved since January 2005, ***86% were in tablet form***, not capsule form. Appendix 5 at A18. And of the 44 new oral tetracyclines—41 are new doxycyclines (either Adoxa or Doryx variants)—which bear the identical FDA label indication for acne: "In severe acne, doxycycline may be useful adjunctive therapy." *See* Appendix 2 at A2.

- **Patent Court Finding of Improved Stability Confirms Benefit of Doryx Tablets over Capsules.** A U.S. District Court held that the '161 patent protecting the new Doryx tablets was valid and that the Doryx tablet patent "***improved the dissolution stability*** of the Capsule."[8] This ruling means that all Plaintiffs' claims, which derive from the capsule-to-tablet "switch," must be dismissed. Plaintiffs seek to avoid this outcome by labeling the District Court's ruling as dicta. But Plaintiffs cannot avoid the reality that central to the court's holding that the tablet patent was not invalid was the stability question: the "problem facing the hypothetical person of ordinary skill in the art is the 'problem of ***improving dissolution stability***' in the Prior Art Doryx Capsule."[9] So clear was the strength of the court's ruling on validity that Mylan did not even attempt to raise the issue on appeal.

- **Additional Benefits of New Doryx.** The undisputed record evidence is that doxycycline capsules such as Doryx were banned in Sweden and France, the subject of a costly recall in 2002 due to stability issues, and were inherently incapable of the flexible dosing a tablet formulation would provide. WC Opp. at 8–13. Only a tablet can be scored, as FDA's own guidance demonstrates. Contemporaneous documents show that consumers preferred tablets to capsules by a 3 to 1 margin.[10] The stronger scored dosage strengths of Doryx—the 150mg and 200mg—permitted once-a-day dosing which increased compliance, a benefit the Mylan witnesses admitted. *See, e.g.*, Malik Tr. 212:4–21, 213:3–13 (Ex. 7). The stronger scored strengths also permitted titration, a large initial dose followed by a maintenance dose, and co-pay savings of a 3-month supply for one prescription. WC Mem. at 55.

- **Barred by Statute of Limitations**. Mylan's alleged damages arise from a discrete 2005 event—the transition from capsules to tablets—and Plaintiffs have identified no evidence to support a continuing violations exception. WC Mem. at 50–52.

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[8] *Impax*, 2012 WL 1551709, at *58 (emphasis added); *id.* at *4 ("The '161 Patent embodies [Mayne's'] solution to the dissolution storage problem."); *see also* WC Opp. at 43–44.

[9] *Impax*, 2012 WL 1551709, at *52 (emphasis added).

[10] [redacted] WC3364650 (Ex. 75).

For the reasons set forth in Defendants' earlier briefs and below, Plaintiffs' claims fail as a matter of law, and summary judgment should be entered as to all of Plaintiffs' claims.

ARGUMENT

I. Because Mylan Never Even Sought FDA Approval For Generic Doryx Capsules, Binding Third Circuit Precedent Requires Dismissal of Plaintiffs' Claims—No Antitrust Standing

In *Ethypharm S.A. France v. Abbott Labs.*, the Third Circuit held that a pharmaceutical plaintiff that—like Mylan here—neither sought nor obtained FDA approval to market a drug lacks antitrust standing. 707 F.3d 223, 237 (3d Cir. 2013). Plaintiffs try to distinguish this binding precedent, arguing that the plaintiff in *Ethypharm* did not have a license to sell in the United States. Mylan Opp. at 28. But *Ethypharm* did not turn on the existence of a U.S. license. The plaintiff's failure to show injury arose, as here, from the plaintiff's lack of FDA approval: "Ethypharm did not suffer antitrust injury because it does not and indeed cannot compete in the United States fenofibrate market, unless and until it acquires the required FDA approval to do so." 707 F.3d at 237.[11] Like Ethypharm, Mylan ***never got approval*** and ***never launched*** the product (generic Doryx capsules) it claimed to be excluded from selling.

Mylan had agreed that the lack of FDA approval defeats antitrust standing in an earlier case in this Court. In 2006, Mylan argued that "[f]ailure to plead tentative approval has alone been held to be sufficient to dismiss antitrust complaints in other cases." Mylan Mem. in Support of its Mot. to Dismiss, *In re Modafinil Antitrust Litig.*, Dkt. No. 27 at 11 (E.D. Pa. Sept. 29, 2006). The rule of *Ethypharm* is fatal to Mylan's case here—as Mylan conceded in

[11] In fact, Plaintiffs simply ignore all the cases Warner Chilcott cites in its opening brief that, like *Ethypharm*, reject antitrust standing unless a pharmaceutical plaintiff has, at a minimum, tentative FDA approval. *See* WC Mem. at 45–46; *see also Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 862 (D.C. Cir. 2008) (not addressed by Plaintiffs) (affirming summary judgment where purchaser plaintiffs failed to "prove [the generic] was prepared to sell Taztia and could have obtained approval from the FDA to do so at some point.").

Modafinil—because Mylan never submitted an ANDA, much less obtained FDA approval (tentative or final), for any generic Doryx capsule formulation.[12] WC Mem. at 44–46.

[redacted] As Mylan Vice President of Global R&D Management William Addicks admitted at his deposition: [redacted] Indeed, Mylan's development of a Doryx capsule was so devoid of effort (and was certainly not successful) that Mylan has moved this Court to allow its fact witnesses to fill chronological gaps using Defendants' documents. *See* Dkt. Nos. 615, 626.

Unable to dispute their own business records and testimonial admissions, [redacted] Plaintiffs' choice of words is peculiar. Plaintiffs' opposition concedes that Mylan could not have entered the market until [redacted] ***at the earliest***—*i.e.*, [redacted] years after beginning development, and over [redacted] years after Mylan could have begun development. *Id.* at 7, 32. Neither *Ethypharm* nor any of the other cases that Defendants discussed in their opening memorandum (WC Mem. at 45–46)—which Plaintiffs ignored—hold that being [redacted] is sufficient to give a pharmaceutical plaintiff

[12] [redacted] (Ex. 445) [redacted].
[13] [redacted] (Ex. 110).
[14] [redacted] (Ex. 113).

antitrust standing. *See also Out Front Prod., Inc. v. Magid*, 748 F.2d 166, 172 (3d Cir. 1984) (failure to show that plaintiffs "went beyond a pessimistic belief" that it was not "worth gearing up to use the facility" resulted in failure to show causation of antitrust injury).[15] There is no such thing as "near" standing.

As the Third Circuit made clear in *Out Front*, where a plaintiff fails to make a serious effort to compete, there is no causation. 748 F.2d at 169–72.[16] Plaintiffs try to distinguish *Out Front* by asserting that "Mylan began preparations to enter the delayed-release doxycycline hyclate market in [redacted] and repeatedly attempted to enter the market, ultimately doing so in 2011." Mylan Opp. at 28 n.38. In 2011, Mylan launched a generic Doryx tablet—not a capsule—a generic of the tablet Warner Chilcott launched in 2005. As discussed above, Mylan's own witnesses confirmed that Mylan simply abandoned development of a generic Doryx capsules in [redacted].[17] Further undermining Plaintiffs' assertion that Defendants somehow impeded development of Mylan's generic Doryx capsules, Mylan discontinued development of generic Doryx capsules [redacted]

[15] *See also Sunbeam Television Corp. v. Nielsen Media Res., Inc.*, 763 F. Supp. 2d 1341, 1357 (S.D. Fla. 2011) (finding company was not potential competitor because it undisputedly "***abandoned*** the television ratings market") (emphasis added), *aff'd*, 711 F.3d 1264 (11th Cir. 2013).

[16] *See also Van Dyk Res. Corp. v. Xerox Corp.*, 631 F.2d 251, 256 (3d Cir. 1980) (no causation where "mishaps" and "misfortune" arose in product development); *Addamax Corp. v. Open Software Found., Inc.*, 152 F.3d 48, 53–55 (1st Cir. 1998) (no causation where alleged losses attributable to plaintiff's decision to "enter[] late").

[17] *See* Kirsch Tr. 149:5–6 (Ex. 113) ([redacted] *see also* Addicks Tr. 167:11–23 (Ex. 110) ([redacted]); Deiriggi Tr. 190:13–25 (Ex. 446) [redacted]

Plaintiffs' amici and Mylan witnesses admit that, without FDA approval, it is not Defendants that have stood in the way of Mylan selling a generic Doryx capsule, it is the FDA.[18] *See* Br. of Intellectual Prop. & Antitrust Law Profs., Dkt. No. 596-3 at 12 ("Regulatory barriers entirely restrict consumer choice between products and eliminate market competition when a product hop occurs."); *id.* at 7 (regulatory framework "prevents" quick generic entry).[19] As a result, Plaintiffs' injuries arise from regulations that antitrust courts are unable to address. *See City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 268 (3d Cir. 1998) ("[T]he interposition of the regulatory scheme and actions of the parties—both defendants and plaintiffs—interferes with the chain of causation. The statutory scheme precluded competition without the requisite regulatory permission.").[20]

II. The "Product Hopping" That Plaintiffs Challenge Is Not Anticompetitive under the Sherman Act—No Illegal Acts

The Court was right on June 12, 2013 to be "skeptical" that Defendants' so-called "product hopping" is illegal under the Sherman Act.[21] Now, almost a year later, the undisputed evidentiary record makes clear that Defendants' "product hopping" is ***not*** anticompetitive. WC Mem. at 2–21; WC Opp. at 24–38. In fact, Mylan fails to cite any evidence showing ***how***

[18] [redacted] (Ex. 445) ([redacted]); (Ex. 389) ([redacted]).

[19] While Plaintiffs' amici provide certain disclosures with their brief, they fail to disclose that Mr. Lemley is not a disinterested professor. Br. of Intellectual Prop. & Antitrust Law Profs., Dkt. No. 596-3. Rather, he was counsel for plaintiffs in the *Tricor* case and has an active practice as a plaintiff's counsel in antitrust cases. *See, e.g., Int'l Bus. Machines Corp. v. Platform Solutions, Inc.*, 658 F. Supp. 2d 603 (S.D.N.Y. 2009) (dismissed on summary judgment); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (affirming grant of summary judgment for defendants); and *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165 (Ct. App. 2011) (affirming grant of summary judgment for defendants), *review granted*, 269 P.3d 653 (Cal. 2012).

[20] *See also RSA Media, Inc. v. AK Media Grp., Inc.*, 260 F.3d 10, 15 (1st Cir. 2001) ("[Plaintiff] was not excluded from the market for outdoor billboards because of AK's threats; it was excluded because of the . . . regulatory scheme that prevents new billboards from being built.").

[21] In this Court's June 12 Order, the Court noted that Plaintiffs' claims are "novel." Order at 3, Dkt. No. 280. Plaintiffs' amici take exception to this characterization, but the only cases they cite involve patent fraud, fraud on the FDA, and other conduct that literally can "exclude" competition. *See* Dkt. No. 596-3 at 10 n.39 (citing *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 351 n.14 (D.N.J. 2009); *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 532 (D.N.J. 2004)). No such conduct is alleged here.

Defendants' innovations were anticompetitive in the first place. Instead, Mylan devotes several pages of its opposition to argue that the applicable antitrust standard is the rule of reason. Mylan Opp. at 10–12. To support application of the rule of reason, Mylan quotes from the Supreme Court's decision in *Standard Oil Co. of New Jersey v. United States*, 221 U.S. 1 (1911). But in the 103 years since the Supreme Court decided that case, no court has ever cited *Standard Oil* to constrain product innovation, as Mylan would have this Court do.

In advocating the rule of reason here, Mylan also cites *Broadcom* to argue: "Conduct that impairs the opportunities of rivals . . . in an unnecessarily restrictive way may be deemed anticompetitive." Mylan Opp. at 10 (quoting *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308 (3d Cir. 2007)).[22] But as noted above, Mylan's witnesses confirmed that Mylan—not Defendants—decided when Mylan would launch (and abandon) a generic product.[23]

Defendants do not dispute that ***if*** their conduct is deemed anticompetitive based on the law and evidence, then the rule of reason would apply (although the evidence shows that the anticompetitive effects do not outweigh the procompetitive benefits). Nor do Defendants need to argue that all instances of so-called "product hopping" are *per se* immune from antitrust scrutiny in order to defeat Plaintiffs' claims on this record. As Plaintiffs admit, under the rule of reason, "a plaintiff must make an initial showing that the conduct it challenges has harmed competition

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[22] Plaintiffs fail to distinguish *Broadcom* from *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57 (3d Cir. 2010)—a more recent Third Circuit case than *Broadcom*. Mylan Opp. at 10 & n.24. Plaintiffs' argument actually confirms that Defendants' conduct here is not anticompetitive. Plaintiffs argue that in *Race Tires*, the conduct "did not actually foreclose the plaintiff," who in fact "secured several contracts in the market." *See* Mylan Opp. at 10 n.24. As noted, however, the testimony of Mylan witnesses Messrs. Workman, Mauro, Kirsch, Addicks, and others actually confirms that—similar to *Race Tires*—Defendants here did nothing to "foreclose" Mylan. Mylan competed against Warner Chilcott and was able to earn a lot more—[redacted] than it expected to earn from capsules. *See* below at Section III(A). This is hardly evidence of foreclosure.

[23] *See* Workman Tr. 173:6–14 (Ex. 388) [redacted]; Mauro Tr. 258:21–259:11 (Ex. 389) [redacted]; *id.* 245:12–20 [redacted]

in some way, such as through exclusion of competitors, increased prices, and/or reduced output in the market." Mylan Opp. at 11. As discussed below, each factor weighs in favor of Defendants, not Plaintiffs: (i) Defendants did not exclude competitors;[24] (ii) Defendants decreased prices;[25] and (iii) Defendants ***increased*** output in the market.[26]

A. Plaintiffs Have Articulated No Viable Test to Assess Whether Defendants' So-Called "Product Hopping" Is Anticompetitive

For Plaintiffs to prevail, the Court must find that Defendants' innovations to Doryx were anticompetitive under the antitrust laws. Absent such a finding, Plaintiffs have no case. But as Warner Chilcott noted in its opening brief (at 11–12), courts have held that it is "not just ***unwise***," but "***unadministrable***" for courts to "weigh the benefits of an improved product design against resulting injuries to competitors." *Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 1000 (9th Cir. 2010) (emphasis added).[27]

Confirming their inability to propose a reliable "innovation test," Mylan's opposition blithely suggests yet ***another*** possible innovation test: Defendants made "***medically unnecessary modifications*** to their products." Mylan Opp. at 12 (emphasis added). Mylan does not have any expert medical evidence defining "medically unnecessary modifications;" instead they cite only the expert reports of their economists, Drs. Rubinfeld and Nelson. Mylan's opposition and the brief of Plaintiffs' supporting amici confirm that an "innovation test" is unadministrable. As Warner Chilcott noted (Mem. at 12–15), Plaintiffs' experts offer an array of loaded phrases to evaluate the "innovativeness" of Doryx—loaded phrases that Plaintiffs'

[24] *See* below at Section II(B).

[25] *See* below at Section IV(A).

[26] *See* below at Section VII(A).

[27] *See also Allied Orthopedic*, 592 F.3d at 1000 ("There are no criteria that courts can use to calculate the 'right' amount of innovation, which would maximize social gains and minimize competitive injury."); *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) ("Courts . . . are not tasked with determining which product among several is superior. Those determinations are left to the marketplace.").

experts could not even define. Recently, Plaintiffs' amici added yet another amorphous, undefined standard to Plaintiffs' litany. *See* Dkt. No. 596-3 at 2 ("***non-substantial*** product changes") (emphasis added). Plaintiffs' shifting standards demonstrate the unworkability of any innovation test. *Compare, e.g.*, Mylan Mem. at 11, Dkt. No. 556 (condemning "incremental[]" scoring changes), *with* Dkt. No. 596-3 at 15 ("[I]nnovation may sometimes come in the form of incremental but genuine improvements . . . .").

Confirming that any innovation test is simply "unadministrable" (just as *Allied Orthopedic* instructs), Plaintiffs' experts conceded that in fact there is "no test."[28] WC Mem. at 14. There is no economic literature at all on product hopping.[29] Perhaps this is because, as Plaintiffs' own experts recognize, "product hopping" itself is a "somewhat diffuse term."[30] By not offering any test, workable or not, Plaintiffs' "diffuse" case theory is at odds with the admonition of the Third Circuit that defendants "deserve a bright-line rule" so they can avoid potential antitrust liability ex ante. *See Race Tires*, 614 F.3d at 80; *see also Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 453 (2009) (expressing need for safe harbors from novel antitrust claim).[31]

As *Allied Orthopedic* teaches, Plaintiffs' "unadministrable" proposal threatens to create "massive" antitrust litigation whenever a manufacturer decides to replace its products, without any bright line rule for manufacturers to follow. As the Third Circuit recognizes, when antitrust

[28] *See, e.g.*, Jackson Tr. 177:3–6 (Ex. 18).

[29] *See* Rubinfeld Tr. 34:20–35:4 (Ex. 2) ("product hopping" is "not a term you would see in a microeconomics textbook").

[30] *See* Rubinfeld Tr. 85:25–86:6 (Ex. 390).

[31] *See also* WC Mem. at 19 (safe harbors proposed by a plaintiffs' expert); Rubinfeld Tr. 36:11–15 (Ex. 390) (opinion as a nonlawyer is that product hopping is "not always illegal"); Leffler Tr. 114:2–15, 199:13–16, 250:21–24 (Ex. 435) (if brand manufacturer is not aware of generic ANDA application, then manufacturer can launch a new branded version and has no duty to keep selling older version).

litigation itself imposes a "chilling effect on competitive market forces," summary judgment for defendant is appropriate. *See Race Tires*, 614 F.3d at 73.

B. The Antitrust Laws Do Not Impose A Duty on Defendants to Aid Their Competitors

Plaintiffs' claims also fail because they presume—contrary to law—that Defendants owe a duty to competitors like Mylan. *See* Mylan Opp. at 15–18. Mylan claims it could have begun selling generic Doryx ***capsules*** in [redacted], or nearly [redacted] ***years after*** Defendants launched Doryx tablets. Mylan Opp. at 7, 32; *see* Appendix 18. Mylan does not—and cannot—deny that Defendants did nothing to block Mylan or any other competitor from launching generic capsules ***at any time***.[32] In fact, another generic manufacturer, Sandoz, got approval for a generic Doryx capsule in December 2005 and launched in July 2006, over a year after Warner Chilcott's tablet was approved.[33] Mylan's complaint is that to make a (speculative) [redacted] launch worthwhile for a generic company like Mylan, Defendants should have kept selling branded Doryx capsules at least until Mylan launched—whether or not Defendants wanted to, and even while Defendants were promoting Doryx tablets. But it is undisputed that Defendants did not know that Mylan was attempting to develop a Doryx capsule. WC Mem. at 19; *see* Appendix 19. Thus, Mylan is necessarily claiming that Defendants—as a matter of antitrust law—had a duty to keep selling branded Doryx capsules just to make it easier for Mylan to sell generic capsules that—at an undetermined time in the future—would undercut Defendants' products.

Of course, the antitrust laws impose no duty on Defendants to aid their competitors—especially at Defendants' expense. *See Trinko*, 540 U.S. at 411 ("[T]here is no duty to aid

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[32] Rubinfeld Rep. ¶11 (Mylan Ex. 2) [redacted]; Ex. 108) [redacted] Ex. 110) [redacted]

[33] [redacted] SANDOZ-RDC-00009404 (Ex. 61).

competitors."); *Brunswick Corp.*, 429 U.S. at 488 (Sherman Act protects "competition, not competitors"); *Race Tires*, 614 F.3d at 75–76.[34] According to Plaintiffs, *Trinko* "is irrelevant as it found no need for antitrust law in light of an alternative regulatory structure that provided competitors market access." Mylan Opp. at 10 n.24. However, the pharmaceutical regulatory regime provides generic companies access to the marketplace. *See id.* at 10, 10 n.24, 14. In light of this "regulatory structure," Defendants had "no duty" to aid Mylan. *See Trinko*, 540 U.S. at 411.[35] Nor do the antitrust laws impose a duty on Defendants to ensure that competitors are able "keep pace with" Defendants, as Plaintiffs would have it (Mylan Compl. ¶71). *See Goldwasser v. Ameritech Corp.*, 222 F.3d 390, 397 (7th Cir. 2000) (not addressed by Plaintiffs) ("[E]ven a monopolist is entitled to compete; it need not lie down and play dead . . . ."); *ILC Peripherals Leasing Corp. v. IBM*, 458 F. Supp. 423, 440–41 (N.D. Cal. 1978) (not addressed by Plaintiffs) (rejecting plaintiff's claim that IBM's product designs made it difficult for plaintiff to "keep pace").[36]

Mylan never owns up to the fact that its Complaint seeks the extraordinary relief of forcing Warner Chilcott to sell a product. Courts consistently have rejected requests to impose an antitrust duty to sell a product. *See Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 925 n.7 (3d Cir. 1999) ("It is appropriate to emphasize that as a

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[34] *See also* Seth Silber & Kara Kuritz, *Product Switching in the Pharmaceutical Industry*, 7 J. Generic Meds. 119, 126 (2010) ("It would still be unchartered territory for a court to create an exception to the general rule that there is no duty to aid competitors in product hopping cases.").

[35] Mylan's proposed distinction that the *Trinko* conduct did not impede market access is also belied by Mylan's own amicus, Professor Mark Lemley, and *Trinko* itself. As Professor Lemley recognized, the *Trinko* plaintiffs alleged that defendant denied competitors "effective access" to facilities "in violation of the underlying regulation." Dogan & Lemley, 87 Tex. L. Rev. at 692–93 (Mylan Ex. 1); *see also Trinko*, 540 U.S. at 407.

[36] *See also Linkline*, 555 U.S. at 450 (no duty to deal under conditions that "rivals find commercially advantageous"); *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1072 (10th Cir. 2013) ("Forcing monopolists to 'hold an umbrella over inefficient competitors might make rivals happy but it usually leaves consumers paying more for less."), *cert. denied*, 2014 WL 833896 (Apr. 28, 2014); *Warner Chilcott v. Impax*, 2012 WL 1551709, at *58 (D.N.J. Apr. 30, 2012) ("[I]t is comforting to know that Warner Chilcott did not run afoul of any antitrust laws by implementing a 'pro-generic' strategy . . . ."); *Apartment Source of Pa., L.P. v. Phila. Newspapers, Inc.*, 1999 U.S. Dist. LEXIS 7744, at *7 (E.D. Pa. May 18, 1999) (no duty to give "helping hand" to competitor).

general rule 'any firm, even a monopolist, may bring its products to market whenever and however it chooses.'"); *Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496, 504 (D.N.J. 2006) ("Indeed, Plaintiff does not cite a single case to suggest the existence of such a duty and courts have routinely held that competitors have no duty to advertise or sell a competitor's products."); *GAF Corp. v. Eastman Kodak Co.*, 519 F. Supp. 1203, 1232 (S.D.N.Y. 1981) ("[T]he ability of the judicial system to determine whether a product should have been marketed and, if so, when is severely limited."). Moreover, the antitrust laws do not require Defendants to market two versions of Doryx at the same time, or otherwise market two products that compete against each other—as Plaintiffs would require. *See Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 867 (D.C. Cir. 2008) ("[N]o provision of law . . . required Biovail . . . to sell . . . a generic version . . . in competition with" itself); *accord Steamfitters*, 171 F.3d at 925 n.7 ("A business's decision to not produce a product, . . . is not a violation of the antitrust laws . . . .").[37]

Here, Defendants did not know that Mylan was developing a generic until 2008 (WC Opp. at 22; *see* Appendix 19), but Plaintiffs would impose a duty on branded manufacturers to find out whether a firm was developing a generic version of Defendants' product before Defendants launched a new version. This presents its own problems under the antitrust laws. *See* 15 U.S.C. § 1.

C. Even if This Court Created a Novel Duty to Sell, It Would Not Benefit Mylan

As discussed above, Mylan asks this Court to impose an unrecognized duty on Warner Chilcott to sell an old version of Doryx until a competitor begins selling a generic version. But even if this duty existed—and this Court should not create it—it would not help Mylan. That is

[37] In fact, one Rule 30(b)(6) witness testified that Warner Chilcott [redacted] (Ex. 396) [redacted]).

because Mylan was ***not the generic*** that would have benefited from Warner Chilcott's compelled continued sales. The undisputed evidence shows that Sandoz, and not Mylan, was the first to develop and launch a generic version of Doryx.[38] In December 2005, Sandoz's generic Doryx capsules were approved for sale by the FDA (Ex. 61; IPP Opp. at 3), thus relieving Warner Chilcott of the continued duty to sell that Mylan proposes.

Mylan does not even claim that it could have been the first to launch a generic Doryx capsule. It claims it could not have sold its first generic Doryx capsule until the [redacted]—and even that claim is not supported by the evidence. And before [redacted], Mylan did nothing even to try to develop a Doryx product for the [redacted] years that branded Doryx was available without patent protection.[39] WC Opp. at 19. Therefore, even under Mylan's novel theory of antitrust, Mylan's claims should be dismissed.

D. Plaintiffs' Novel Case Does Not Involve Traditional Acts of Monopolization—Exclusive Contracts, Tying Arrangements, Patent Misuse, or Similar Conduct—or Coercion

It is undisputed that Defendants' conduct did not involve the hallmarks of anticompetitive conduct: exclusive contracts, tying arrangements, predatory pricing, patent conduct, or any patent misuse. WC Mem. at 7–9.[40] Yet Mylan asserts that "Defendants' conduct foreclosed ***any*** efficient means of distribution for an AB-rated generic version of Doryx, which delayed entry by Mylan and allowed Defendants to pocket ill-gotten profits for years." Mylan Opp. at 1 (emphasis added). Mylan cites nothing to support this broadside. In addition, as discussed above, eight Mylan witnesses testified that Defendants did not impede Mylan's development of generic Doryx capsules or impede access to their customers. *See* Sections II(F), III(A).

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[38] [redacted] SANDOZ-RDC-00003364 (Mylan Ex. 99).

[39] Addicks Tr. 81:7–25 (Ex. 437) ([redacted]; Appendix 18. *See also* Rubinfeld Tr. 17:1–13 (Ex. 2) ([redacted]); Nelson Tr. 102:18–23 (Ex. 28) ([redacted]).

Mylan also contends that Defendants' conduct is anticompetitive because it was "sufficiently coercive." Mylan Opp. at 13. For Section 2 antitrust claims, however, the Third Circuit has defined coercion as "measures that ***prevented*** [a competitor] from selling its products to any willing buyer or ***prevented*** others from dealing with [the competitor]." *Race Tires*, 614 F.3d at 78 (emphasis added) (citing *Santana Prods. Inc. v. Bobrick Washroom Equip.*, 401 F.3d 123, 132 (3d Cir. 2005)). Defendants never prevented Mylan from "selling its products" and never prevented "others from dealing" with Mylan. *See* WC Mem. at 7–9.

Confirming that Mylan was not foreclosed here, Mylan does not dispute that it could have introduced and sold a generic version of the Doryx capsule at any time from 1985 to the present. *See* Mylan Opp. at 7 (Mylan refocused its business efforts on Doryx tablets after tablet launch). Mylan simply [redacted] do so. WC Opp. at 53. When it has chosen to, Mylan has sold generic copies of old versions of branded Doryx after a new branded Doryx version has been introduced, unconstrained by Defendants. For example, Mylan continues to sell the 75 and 100mg scored Doryx tablets which Warner Chilcott ceased distributing in March and August 2011, respectively. *See* WC Opp. at 23; Appendix 24.

To the extent any customer's choice of Doryx products was limited, that is because generic manufacturers like Mylan chose not to sell competing versions. *See* above Section II. Otherwise, compelling Warner Chilcott to make an older version available to customers would assume a duty to market that does not exist under the Sherman Act. *See* above Section II.B.

The IPPs cite (Opp. at 6–7) only cases involving actual coercion or complete foreclosure—conduct far removed from that alleged here. *See Theme Promotions, Inc. v. News Am. Mktg. FSI*, 546 F.3d 991, 1003–04 (9th Cir. 2008) (right of first refusal agreements "forced" advertiser to buy inserts from Defendant instead of existing competitor); *Glen Holly Entm't Inc.*

v. Tektronix Inc., 343 F.3d 1000, 1011 (9th Cir. 2003) (agreement between "only two competitors" in marketplace to discontinue *only* "competing product on the market" prevented users from switching products) (emphasis added); *Xerox Corp. v. Media Scis. Int'l Inc.*, 511 F. Supp. 2d 372, 381, 382 (S.D.N.Y. 2007) (lock-in agreements "not to sell" product in marketplace where "no competitors [are] able to enter").

Aware that its coercion argument is unpersuasive, Mylan argues in the alternative that Defendants' conduct need not have been coercive at all. *See* Mylan Opp. at 13. But Mylan's alternative position also fails. As discussed more fully in Warner Chilcott's opposition to Mylan's summary judgment motion, when new products are involved, courts will not condemn conduct under the antitrust laws unless the conduct involves "coercion." WC Opp. at 36–38.

E. Congress and the FDA, Not Courts, Resolve "Regulatory Gaming"

Plaintiffs' "regulatory gaming" argument runs counter to the goals of the Hatch-Waxman Act. WC Opp. at 26–30. Far from requiring branded manufacturers to slow their innovations, the Hatch-Waxman Act seeks to accelerate research and development by branded firms so that their innovations may more quickly come to market.[41] As Senator Orrin Hatch, one of the Hatch-Waxman Act's chief sponsors and namesakes explained:

> [T]he number of beneficial new drugs, and consequently our national leadership in this field, will increase as research and development expenditures increase. . . . The added research and development will flow from added patent protection which will compensate the research drug companies for the years of exclusive marketing time under their patents lost because of the lengthy FDA testing and review period. . . . The bill truly promises us . . . better drugs tomorrow.[42]

[41] [redacted] (Ex. 445) [redacted]).

[42] *Drug Price Competition and Patent Term Restoration Act of 1984, Hearing on S. 2748 Before the S. Comm. On Labor & Human Res.*, 98th Cong. 1, 1–2 (statement of Sen. Orrin Hatch, Chairman) (Ex. 393); *see also* H.R. Rep. No. 98-857, at 41 (Ex. 394) ("The Committee expects that research intensive companies will have the necessary incentive to increase their research and development activities."); *Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135,

In fact, Plaintiffs' own experts recognize that the incentives for brand companies to innovate are a matter of [redacted] *See, e.g.*, [redacted] (Ex. 395).

Having failed to persuade Congress and the FDA to change the bargain struck by the Hatch-Waxman Act (WC Opp. at 27–28), Plaintiffs now ask this Court to do so. But as discussed in Warner Chilcott's opposition to Mylan's summary judgment motion, Congress is capable of amending Hatch-Waxman when it sees fit to do so. WC Opp. at 27–28. Its determination of when to amend the law and when not to should be respected by parties and courts.

F. The Sherman Act Protects Defendants' Pro-Competitive "Anti-Generic Strategy"

Mylan's opposition confirms this is a one fact case. Because Mylan cannot identify any anticompetitive conduct, Mylan is forced to rely on references in documents to an "anti-generic" strategy. *See, e.g.*, Mylan Opp. at 6. But Mylan does not and cannot dispute that—even though Defendants launched Doryx tablets in 2005—Defendants did not know Mylan was planning to launch any generic version of Doryx until December 2008 (*i.e.*, ***three years*** after Warner Chilcott had launched the tablets).[43]

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139 (3d Cir. 1987) (Hatch-Waxman Act protects interest in "the research investments of the pioneer manufacturers").

[43] [redacted] MYLAN-01603636 (Ex. 228); *see* Appendix 19. Before the October 2008 QI Act, Warner Chilcott would not have received notice of generic manufacturers seeking to launch a competing version of Doryx. *See generally* QI Program Supplemental Funding Act of 2008, Pub. L. 110-379, § 4, 122 Stat. 4075, 4076–78 (Ex. 399). The only evidence cited by Plaintiffs that Warner Chilcott knew of any potential generic Doryx development are [redacted]. [redacted] WC1650289, at 292 (Mylan Ex. 58). [redacted] WC1574454 (Ex. 449); [redacted] WC1104347 at 53 (Ex.450).

Plaintiffs cannot deny that generic manufacturers are ***competitors*** of branded manufacturers, [redacted].[44] Such strategies are standard in the pharmaceutical industry, not only with Mylan but with other makers of acne treatments, such as Solodyn and Dynacin.[45] Plaintiffs' fixation on Warner Chilcott's anti-generic strategy is nothing new. As the Doryx patent court declared, "it is comforting to know that Warner Chilcott did not run afoul of any antitrust laws by implementing a "***pro-generic" strategy***." *Mylan*, 2012 WL 1551709, at *58 (emphasis added).

Anti-competitor strategies are protected by the Sherman Act. *See Alberta Gas Chems., Ltd. v. E.I. Du Pont de Nemours & Co.*, 826 F.2d 1235, 1239 (3d Cir. 1987) (not addressed by Mylan) ("Conduct that harms competitors may benefit consumers—a result the antitrust laws were not intended to penalize.").[46] Here, Plaintiffs cannot deny that Defendants' "anti-generic" strategy increased competition, including through new products and more sales. WC Mem. at Appendix 20 (Nelson Rep. Ex. 8) (40-fold increase in Doryx unit sales from 1997 to 2010); WC Opp. at 2 & Table 1 (Doryx annual sales rose from $1.7 million in 1997 to $410.4 million in 2010); Appendices 20, 21. Ironically, it is Defendants' competitive efforts that attracted Mylan's interest in the Doryx franchise, resulting in Mylan earning [redacted] million in profits selling generic Doryx tablets.[47] As Plaintiffs concede, some generic manufacturers competed very successfully against branded Doryx and other tetracyclines in the marketplace. WC Mem. at 18–

[44] [redacted] (Ex. 271); *see also* [redacted] (Ex. 445) ([redacted]).

[45] Nelson Patent Decl. ¶82 (Ex. 395) ([redacted]).

[46] *See also Novell, Inc.*, 731 F.3d at 1078 ("Were intent to harm a competitor alone the marker of antitrust liability, the law would risk retarding consumer welfare by deterring vigorous competition . . . ."); *A.A. Poultry Farms, Inc. v. Rose Acre Farms, Inc.*, 881 F.2d 1396, 1402 (7th Cir. 1989) ("Intent does not help to separate competition from attempted monopolization and invites juries to penalize hard competition."); *see also* WC Mem. at 19–20.

[47] WC Mem. at Appendix 7 (Nelson Rep. Ex. 31).

19; *see also* Mylan Opp. at 7 (conceding Doryx generic entrant had "impact"); *Race Tires*, 614 F.3d at 84 (no antitrust liability where plaintiff "did compete, sometimes successfully").

Finally, Mylan claims that "Defendants cannot dispute that their 'anti-generic strategy' succeeded in delaying generic entry." Mylan Opp. at 6. The fact is that—as discussed above—Mylan's own witnesses have testified that Defendants did not prevent Mylan from developing or selling [redacted][48]

G. Mylan's Admission that Its Own Product Hopping on EpiPen Was Not Anticompetitive Prevents Mylan from Challenging Defendants' Conduct Here

Mylan argues there is no evidence that its changes to EpiPen constituted anticompetitive conduct. Mylan Opp. at 15. Defendants agree. Yet, Mylan's conduct with EpiPen is on all fours with the type of conduct Mylan purports to challenge here. Mylan launched new versions of the EpiPen and

[49] [redacted] Mylan did not continue to sell older versions of the EpiPen. *Compare* [redacted] (Ex. 36), *with* Mylan Opp. at 4–5 (Defendants introduced new products and "ceased distribution" of old products). In light of the success of Mylan's EpiPen strategy, Mylan appears to be pursuing an anti-generic strategy of its

[48] [redacted] (Ex. 388); *see also* [redacted] (Ex. 443) [redacted]); [redacted] (Ex. 444) [redacted]); [redacted] (Ex. 389) ([redacted]); [redacted] (Ex. 445) ([redacted]). [redacted] (Ex. 389) [redacted].

[49] [redacted] MYLAN-01238087 (Ex. 34); *see also* [redacted] MYLAN-00609013 (Ex. 35) [redacted]

own.[50] The Court should accept Mylan's EpiPen position: removing an old version of a branded drug, even to create an impediment to generics, is not anticompetitive under the Sherman Act.

Moreover, as the Third Circuit has recognized, a Section 2 plaintiff's own practice raises a "serious flaw" in its case when a plaintiff challenges the same practice. *See Race Tires Co.*, 614 F.3d at 82 ("STA's whole challenge to the single tire rule has a simple yet serious flaw. It was [plaintiff] *STA* that actually pioneered and promoted the whole idea in the first place."); *see also Nokia Corp. v. Apple Inc.*, 2011 WL 2160904, at *3 (D. Del. June 1, 2011) (permitting defense "that Apple should be estopped from alleging that Nokia engaged in anticompetitive conduct comparable to Apple's own conduct," and distinguishing *in pari delicto* defense).

III. Plaintiffs Lack Antitrust Standing—No Causation

As discussed above in Section I, because Mylan never even sought FDA approval for generic Doryx capsules, Plaintiffs have no standing. In addition, contrary to Mylan's opposition (at 26–31), Plaintiffs also lack antitrust standing for failure to prove the requirements of antitrust injury, causation, and non-speculative damages. WC Mem. at 39–50.

A. Plaintiffs Have Suffered No Antitrust Injury Because Defendants Did Nothing to Prevent Their Competitors from Launching

To prevail in this case, Plaintiffs must prove that they suffered antitrust injury, *i.e.*, "injury of the type the antitrust laws were intended to prevent." *Brunswick Corp.*, 429 U.S. at 489. As Plaintiffs concede in their opposition, no antitrust violation may be found where the defendant's conduct "did ***not actually foreclose*** the plaintiff" from competing. Mylan Opp. at 10 n.24 (emphasis added) (citing *Race Tires*, 614 F.3d at 74). As discussed above, Mylan could have developed and sold generic Doryx capsules but [redacted] and instead switched its

[50] Mylan Inc. at Bank of America Merrill Lynch Health Care Conference 9 (May 14, 2014) (remarks of Mylan CEO Heather Bresch) (Ex. 402) ("[W]e have continued to look and have said we would add to our respiratory franchise. We currently have in development a combo product that would be a follow-on to our Perforomist franchise.").

efforts and successfully developed generic Doryx tablets. In fact, Mylan's success in the marketplace—earning over [redacted] in profits selling generic Doryx tablets[51]—belies any alleged market foreclosure.[52] As in *Race Tires*, where the court found no antitrust injury, Mylan and others "had the clear opportunity to compete and did compete." 614 F.3d at 84; *see also* Mylan Opp. at 7 (generic entry on 75 and 100mg Doryx capsules had "impact"); WC Opp. at 23 (Mylan competed on certain Doryx versions). Because Plaintiffs concede that Defendants did not prevent Mylan or any other competitor from selling a generic product, Plaintiffs have failed to establish that Defendants' alleged "product hopping" caused them any competitive injury.[53]

Incredibly, Plaintiffs' experts have proven that Plaintiffs suffered ***negative damages***. In 2005, Mylan estimated that it would earn—[redacted] in gross margin on generic Doryx capsules over the first four years.[54] In the real world, Mylan launched its generic Doryx 75 and 100mg tablets in December 2010, becoming the only generic Doryx tablet on the market and receiving 180 days exclusivity.[55] Mylan later obtained approval for 150mg Doryx tablets.[56] Mylan's expert Dr. Nelson calculates Mylan's actual gross profits on generic Doryx tablets—made possible by Defendants' conduct—at ***more than*** [redacted] for just over three years.

[51] WC Mem. at Appendix 7 (Nelson Ex. 31).

[52] [redacted] (Ex. 2) [redacted].

[53] [redacted] (Mylan Ex. 2) [redacted]).

[54] [redacted] MYLAN-01107595 (Ex. 260) ([redacted]

[55] [redacted] MYLAN-00017182 (Mylan Ex. 213).

[56] [redacted] MYLAN-00017183 at 183–84 (Mylan Ex. 219).

Having suffered no damages—and instead prospering greatly—Plaintiffs' case must be dismissed. *See Race Tires*, 614 F.3d at 84 (plaintiff "had the clear opportunity to compete and did compete, sometimes successfully"). A contrary result would punish the very conduct the antitrust law protects. *See Trinko*, 540 U.S. at 414 ("Mistaken inferences and the resulting false condemnations are especially costly, because they chill the very conduct the antitrust laws are designed to protect. The cost of false positives counsels against an undue expansion of § 2 liability.").[57]

B. The [redacted] Capsule Entry Date That Plaintiffs Conjure Is Rank Speculation

Additionally, Plaintiffs' suggestion that Mylan could have launched generic Doryx capsules in [redacted] is wholly speculative and does not raise a triable issue that Plaintiffs suffered damages. *See, e.g.*, Mylan Opp. at 48 (stating in one conclusory sentence that Mylan "has provided more than enough evidence to demonstrate damages").

[57] *See also* Dogan & Lemley, 87 Tex. L. Rev. at 729 (Mylan Ex. 1) ("[R]egulatory gaming may resemble conduct that is neutral or procompetitive, raising the risk that antitrust enforcement will create false positives.").

As noted, Mylan never had a viable generic Doryx capsule formulation, never drafted a generic Doryx capsule ANDA, and never submitted a generic Doryx capsule ANDA to the FDA.[58] Indeed, at the time Mylan abandoned development, [redacted][59] [redacted][60] [redacted] Plaintiffs' damages claim is purely speculative. *See* WC Mem. at 47 ([redacted]); *City of Pittsburgh*, 147 F.3d at 268 ("The injury is not only 'speculative' because it is difficult to measure; rather, it is speculative because the injury claimed may never occur."); *Twin Cities Bakery v. Biovail Corp.*, 2005 U.S. Dist. LEXIS 5570, at *14, *20 (D.D.C. Mar. 31, 2005) (granting summary judgment where FDA approval of third party's ANDA was "fundamentally speculative" after dissolution failures and manufacturing problems).

IV. Plaintiffs Cannot Establish a Narrow, Doryx-Only Product Market, and Doryx Is Not a Monopoly

The undisputed evidence in this case establishes that Doryx competes in a crowded and highly competitive market of branded and generic oral tetracyclines,[61] and that competition from

[58] *See* [redacted] (Ex. 421) [redacted].

[59] [redacted] (Ex. 108).

[60] [redacted] (Ex. 110) [redacted] (emphasis added); [redacted] MYLAN-02090237 at 239 (Ex. 135) ([redacted].

[61] *See, e.g.*, [redacted] FOUGERA000051 at 56 (Ex. 403) [redacted]; [redacted] MED-WCS0000472 at 492 (Ex. 79) [redacted] MED-

these acne products that are not AB-rated to Doryx has animated Defendants' conduct since at least 1997.[62] Mylan, however, asks this Court to ignore this overwhelming evidence and instead find—against the record and common sense—that Plaintiffs might still be able to prove a nonsensical Doryx-only market at trial. Mylan Opp. at 25–26. The Court should reject Plaintiffs' groundless alleged product market. *See Harrison Aire, Inc. v. Aerostar Int'l, Inc.*, 423 F.3d 374, 383 (3d Cir. 2005) (not addressed by Plaintiffs) (affirming summary judgment for defendants, stating: "Relevant market definition is a function of reasonably available product substitutes."); *see also Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 437 (3d Cir. 1997) (not addressed by Plaintiffs) ("[T]he outer boundaries of a relevant market are determined by the interchangeability of use.").

A. Overwhelming Evidence Shows That the Relevant Product Market in This Case Includes at Least All Oral Tetracyclines Used for Acne

There is no genuine dispute: All material facts confirm the relevant product market is broader than branded and generic Doryx. WC Mem. at 21–39; WC Opp. at 61–72.

Doryx competes in a crowded and highly competitive market of oral tetracyclines. Plaintiffs argue that "Doryx is sufficiently differentiated to constitute a separate relevant market." Mylan Opp. at 20. But simply asserting that does not make it so. That Warner

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WCS0000036 at 045 (Ex. 82) ( ); WC1075125 at 129 (Ex. 404) (Ex. 405)); (Ex. 406)).

[62] MA-0266524 (Ex. 131)); *id.* at 525 WC0177375 at 378 (Ex. 173) ; WC1095716 at Slide 8 (Ex. 176) WC1876783 at Slide 26 (Ex. 180)); WC1047535 at Slide 7 (Ex. 182) (.

Chilcott tried to exploit Doryx's side effect profile in competition with other acne treatments—treatments with the same FDA-approved label indication for acne—to maintain and take sales only confirms the fierce competition and interchangeability among oral tetracycline antibiotics.[63]

Doryx competes on price with many non-AB-rated products. Plaintiffs next attempt to avoid summary judgment by arguing that AB-rated generics are "the only products capable of significantly constraining Doryx pricing." Mylan Opp. at 21. This too ignores undisputed evidence, including the success of Warner Chilcott's Doryx coupon program. Coupon activity shows that Doryx pricing was constrained by non-AB-rated products. *See* WC Opp. at 70–72.[64] For example, Warner Chilcott introduced a coupon program for Doryx capsules in [redacted]—months before Sandoz's generic Doryx product was approved.[65] Warner Chilcott's internal marketing documents from that time identify the "Target Priorities" for the Doryx coupon as: [redacted][66] When the FDA approved Warner Chilcott's Doryx tablet in 2005, Warner Chilcott extended the coupon program to include the new tablet.[67] Since then, price changes in the broader oral tetracycline market caused price changes to the Doryx tablet coupon. Competition from other brands and generics—[redacted] caused Warner Chilcott to change its Doryx tablet coupon from a fixed-amount coupon to a more

[63] *See* WC Opp. at 62–63; *see also* [redacted] (Ex. 405) [redacted]); [redacted] MPC038535 ([redacted].

[64] [redacted] (Ex. 395).

[65] [redacted] WC1096349 at Slides 41–53 (Mylan Ex. 18); [redacted] WC0638813 (Ex. 408).

[66] [redacted], WC1096349 at Slide 52 (Mylan Ex. 18). [redacted] *See* [redacted] FOUGERA000333 (Ex. 410).

[67] [redacted], WC0638813 (Ex. 408).

generous "pay no more" coupon in 2009, for example.[68] Similarly, Warner Chilcott brought back a "pay no more" coupon in August 2011 because [redacted][69]

Plaintiffs' own economists have acknowledged that the Doryx coupon program was a way for Warner Chilcott to compete on price with non-AB-rated products. Mylan's Dr. Rubinfeld admits that Warner Chilcott was couponing Doryx for more than four years before Mylan received FDA market approval for its generic Doryx tablet, and that Warner Chilcott's couponing expenditures during that time were upwards of [redacted] percent of Doryx gross sales:

[redacted]

[68] [redacted] WC0745301 at Slides 11–13, 15–16 (Ex. 63). Warner Chilcott's planning documents show that the introduction of the "pay no more" Doryx coupon program was also an attempt to compete on price with other oral tetracyclines, and in particular generic immediate-release doxycycline. [redacted] WC0528121 at Slides 29–30 (Ex. 42).

[69] [redacted] WC3355209 at 213 (Ex. 411); [redacted] ([redacted]; [redacted] WC1282132 at 133 (Ex. 412) ([redacted]).

Rubinfeld Rep. Ex. 10 (Mylan Ex. 2) (shading and other modifications added). [redacted] [70] Moreover, Plaintiffs have conceded that Mylan's generic Doryx was actually [redacted] to patients than Warner Chilcott's branded Doryx when factoring in coupons.[71]

Branded and generic oral tetracyclines are close substitutes for Doryx. Mylan admits that "there was some competition between Doryx and other products" but claims—incorrectly—that oral tetracyclines other than Doryx's AB-rated generics are "poor substitutes" for Doryx. Mylan Opp. at 21–22. The record is clear that dermatologists consider oral tetracyclines to be close substitutes and similarly effective acne therapies. WC Mem. at 25–26; WC Opp. at 64, 67–68.[72] As Plaintiffs' own dermatology expert, Dr. Jackson, testified: [redacted] [73] *See Queen City Pizza*,

[70] [redacted] (Ex. 395). [redacted] *Id.*; *see also id.* ¶92 [redacted]

[71] [redacted] Mylan Ex. 2) [redacted] ; [redacted] (Ex. 413) ([redacted]); *see also* [redacted]); [redacted]

[72] Nelson Patent Decl. ¶18 (Ex. 395) [redacted]

[73] Jackson Rep. ¶69 (Ex. 11) (emphasis added); *see* Jackson Tr. 298:13–299:7 (Ex. 415) ([redacted]); Webster Rep. ¶15 (Ex. 38) [redacted]); *see also* Orlando Tr. 87:19–92:7 (Ex.

124 F.3d at 437 ("Interchangeability implies that one product is roughly equivalent to another for the use to which it is put; while there may be some degree of preference for the one over the other, either would work effectively.").

Further confirming that oral tetracycline products are interchangeable, they all share the same FDA-sanctioned label.[74] Moreover, the evidence adduced by Plaintiffs' experts confirms that Doryx competes with such products as [redacted] and that some of these products are ***more expensive than Doryx***.[75]

Undisputed ***evidence*** also makes clear that managed care organizations consider branded and generic oral tetracycline antibiotics to be close substitutes for Doryx. *See* WC Mem. at 26–27; WC Opp. at 64, 67. Using formularies, step-edits, and other tools,[76] managed care organizations have steered patients away from Doryx to other oral tetracycline products[77] (in contrast to Mylan Opp. at 21) that managed care committees determined to be ***therapeutic alternatives*** to Doryx.[78] These committees are made up of practicing physicians and pharmacists committed to patient care.[79] There is simply no reliable evidence to support Plaintiffs' assertion that AB-rated generics are the only close substitutes for Doryx—not even from their own experts.

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400) (testifying that Doryx and immediate-release doxycycline hyclate [redacted] once in the body).

[74] WC Mem. at 23–24 & Appendix 2 (discussing labels).

[75] *See* Nelson Rep. Exs. 18A, 19, 21A, and 23 (Mylan Ex. 19); [redacted]

See Nelson Patent Decl. ¶26 (Ex. 395) [redacted].

[77] [redacted] Verscharen Ex. 27, WC0317972 at 979 (Ex. 416) [redacted]).

[78] WC Mem. at 26; *see also* [redacted] (Ex. 405) [redacted] (Ex. 417) [redacted]

[79] [redacted] (Ex. 405).

FDA approval of over 40 oral tetracycline products since 2005 establishes ease of entry. Plaintiffs' argument that the market in which Doryx competes has high entry barriers (Mylan Opp. at 21–22) fails for the reasons discussed in Warner Chilcott's opening brief, including that the tetracycline market has been characterized by rapid entry. WC Mem. at 34 & Appendix 5.[80] As the Third Circuit succinctly put it: "Absent this *sine qua non* [entry barriers], there is no violation of the Sherman Act." *Handicomp, Inc. v. U.S. Golf Ass'n*, 2000 WL 426245, at *4 (3d Cir. Mar. 22, 2000); *see also* WC Mem. at 34 (listing cases). Plaintiffs deny none of this.

B. Plaintiffs Fail to Rebut Dr. Addanki's Conclusions That the Relevant Product Market Is Broader than Doryx Alone

Mylan's primary response to Dr. Addanki's analysis is to mischaracterize it. Mylan Mem. at 32–33; Mylan Opp. at 22–25. Mylan's arguments are unfounded and ignore that Defendants moved for summary judgment based on the admissions of Mylan's own experts, Drs. Nelson and Rubinfeld. *See, e.g.*, WC Mem. at 2, 7, 12–13, 45.

First, Mylan claims that Dr. Addanki's analysis is "junk science." Mylan Opp. at 22. The truth is Dr. Addanki conducted a rigorous regression analysis based on "accepted" and "regularly used" scientific methods—in the words of Plaintiffs' experts.[81] Mylan's experts applied no science at all.[82]

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[80] *See also* Rubinfeld Tr. 271:14–23 (Ex. 390) (testifying that the marketplace for oral antibiotics for acne is "dynamic").

[81] Nelson Tr. 35:13–19 (Ex. 421) [redacted]; Rubinfeld Tr. 266:7–266:14 (Ex. 2) [redacted] Nelson Tr. 35:20–36:25 (Ex. 421) [redacted] ; Rubinfeld Tr. 265:24–266:6 (Ex. 2) [redacted]

Second, Dr. Addanki does not assert—as Mylan claims—that "market power derived from marketing activities does not amount to meaningful market power." Mylan Opp. at 23. Rather, he explains that the existence of a ***price premium*** (i.e., price over marginal cost) by itself tells us nothing about whether a company actually exercises market power.[83] To take the contrary position—as Plaintiffs do—is to say that every company making a profit is a monopolist. Thus, Dr. Addanki's position is in no way "out of step" with either governing law or standard economics, as Mylan would have this Court believe. Mylan Opp. at 23. As explained by two leading antitrust economists:

> More often than not, firms with Lerner Indices large enough to indicate significant market power are not "monopolies" in the traditional antitrust sense that emphasizes heavy-handed output constraints and the absence of competition. Rather, these firms' price-cost margins may reflect "superior skill, foresight and industry" that is the *very result of competition*. Or, a relatively high Lerner Index may reveal nothing more than the necessity of covering fixed costs.[84]

To assess whether, as an economic matter, Warner Chilcott possessed the sort of market power with Doryx that gives rise to competitive concerns, Dr. Addanki performed a comprehensive analysis of the market in which Doryx is sold and the forces that have combined to create demand for Doryx. The assessment undertaken by Dr. Addanki is necessary because, as Dr. Addanki testified,

> [i]f you engage in demand-building activities, those affect the demand curve for your product. Your optimum price as that demand curve moves will change. . . . [I]f a change

[redacted]

Addanki Rep. ¶¶12–24 (Ex. 53).

[84] Kenneth G. Elzinga & David E. Mills, The Lerner Index of Monopoly Power: Origins and Uses, 101 *Am. Economic Review* 558, 561–62 (2011) (Ex. 339) ("Courts have been hesitant to infer the existence of market (or monopoly) power from evidence based on the Lerner Index alone."); *see also* Louis Kaplow & Carl Shapiro, "Antitrust," in *Handbook of Law and Economics* (2007) (Ex. 418) ("Given the near ubiquity of some degree of technical market power [as indicated by a Lerner Index of significant magnitude], the impossibility of eliminating it entirely, and the inevitable costs of antitrust intervention, the mere fact that a firm enjoys some technical market power is not very informative or useful in antitrust law."); Benjamin Klein, Market Power in Antitrust: Economic Analysis after *Kodak*, 3 *Sup. Ct. Econ. Rev.* 43 (1993) (Ex. 419) (warning that price premium may not be informative about a company's ability to raise market price and/or constrain market output).

> was engendered by a movement of the demand curve that resulted from demand-building activities, I would not view that as an exercise of market power in any antitrust sense. . . . [T]he idea that your optimum pricing might change for reasons having to do with movements in your demand curve that were engendered by demand-building activities, the idea that that has nothing to do with an increase in monopoly power is not something I . . . would expect to have any particular dissent about in the economics profession.[85]

The potential demand-building effects of advertising and promotion (*i.e.*, that they cause an outward shift of the demand curve for the promoted products such that "more goods will be bought at any given price") are uncontroversial in economics.[86] Accordingly, Dr. Addanki stated in his expert report: "Premiums that are purely the result of brand and demand building activities are . . . simply the economic returns of those efforts. They do not connote monopoly power."[87]

Third, Plaintiffs incorrectly assert that Dr. Addanki's analysis is untethered to the "competition question in this case." Mylan Opp. at 23.[88] This bald assertion is misguided according to even Mylan's economists. Indeed, Dr. Addanki's regression analysis is exactly the kind Mylan's own expert, Dr. Rubinfeld, has used to define a product market. *See State of New York v. Kraft Gen. Foods*, 926 F. Supp. 321, 356–57 (S.D.N.Y. 1995) (admitting Dr. Rubinfeld's regression analysis of cereal pricing). Furthermore, Dr. Addanki's regression analysis here is exactly the kind that the FTC's own administrative law judges have accepted from Dr. Addanki to define a relevant product market. *See generally In re Schering Plough Corp.*, 335 F. Supp. 2d 522 (F.T.C. June 27, 2002) (Chappell, A.L.J.).

It is the Plaintiffs' proposed relevant market that is "out of step" and contrary to undisputed market realities. *See Town Sound & Custom Tops, Inc., v. Chrysler Motors Corp.*, 959 F.2d 468, 480 (3d Cir. 1992) (en banc) (not addressed by Plaintiffs) ("Except in rare

[85] Addanki Tr. 38:12–40:15 (Ex. 420); *see also* Addanki Rep. ¶¶13–24 (Ex. 53).

[86] *See, e.g.*, William J. Baumol & Alan S. Blinder, *Economics: Principles and Policy* 492 (4th ed. 1988) (Ex. 442).

[87] Addanki Rep. ¶21 (Ex. 53).

[88] Plaintiffs oddly claim that Dr. Addanki has admitted that he did not consider the competition question at issue in this case. Mylan Opp. at 23. But Dr. Addanki has made no such admission; he explicitly testified to the contrary. *See* Addanki Tr. 20:12–25, 60:11–23, 263:3–267:21 (Ex. 420).

circumstances, courts reject market definitions consisting of one supplier's products where other brands compete."); *Edward J. Sweeney & Sons, Inc. v. Texaco, Inc.*, 637 F.2d 105, 118 (3d Cir. 1980) (not addressed by Plaintiffs) ("Accepting these arguments would lead to the conclusion that every manufacturer of a trademarked product has monopoly power over that product. No legal precept stands for this proposition . . . ."); *In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 683 (D.N.J. 2005) ("Plaintiffs' approach, if applied beyond this case, would render most brand name pharmaceutical companies as per se monopolists prior to generic entry.").

Fourth, Plaintiffs' assertion that Dr. Addanki inaccurately identified the products that constrain Doryx prices is misleading. Mylan Opp. at 24.[89] Dr. Addanki's analysis shows that, as an economic matter, Doryx competes in a broad market for all oral antibiotic products that are used to treat acne. Addanki Rep. ¶¶30–125 (Ex. 53). He adduces this through an analysis of the extensive evidence of price-based and non-price-based competition in that market at the physician, payor, and patient levels. He has identified substantial evidence of competition between sellers of oral tetracycline antibiotics for marginal consumers, including a regression analysis that shows statistically significant diversion of prescribing activity from Doryx to other oral tetracycline antibiotic products in response to an increase in the price of Doryx. *Id.*; WC Mem. at 34–36; WC Opp. at 70–72. While Mylan argues that Dr. Addanki's econometric analysis did not show a statistically significant connection between Doryx and all oral tetracyclines, Mylan Opp. at 25, Mylan omits that Dr. Addanki's analysis shows a statistically

[89] Assuming *arguendo* its utility in the context of antitrust conduct cases (*see* WC Opp. at 66–67), Mylan has mischaracterized and selectively quoted from the Merger Guidelines. Mylan Opp. at 24 (citing *Merger Guidelines* § 4). In particular, the sentence immediately following the passage quoted by Mylan ***counsels against*** Plaintiffs' narrow proposed relevant product market: "[A] group of products is too narrow to constitute a relevant market if competition from products outside that group is so ample that even the complete elimination of competition within the group would not significantly harm either direct customers or downstream consumers."

significant relationship and meaningful restraining effect between Doryx and Adoxa, generic immediate-release doxycycline hyclate, and generic doxycycline monohydrate—***any of which*** would be fatal to Plaintiffs' monopolization case if included in the relevant market.[90] In short, Dr. Addanki's report confirms what is clear in contemporaneous documents from Warner Chilcott and its brand-name competitors: there is vigorous competitive activity among all oral tetracycline antibiotic products.

C. Plaintiffs' Purported "Direct Evidence" Cannot Save Plaintiffs from Summary Judgment

To prove monopoly power through direct evidence,[91] Plaintiffs must provide "evidence of supracompetitive prices and restricted output." *See Broadcom Corp.*, 501 F.3d at 307; *Harrison Aire, Inc.*, 423 F.3d at 381 (noting "direct proof is ***only rarely available***") (emphasis added); *In re Neurontin Antitrust Litig.*, 2013 WL 4042460, at *5 (D.N.J. Aug. 8, 2013) ("While there may be other ways to prove monopoly power, proof of supracompetitive pricing cannot stand alone here.");[92] *Remeron*, 367 F. Supp. 2d at 681 n.10 ("[W]ithout evidence that sheds light on material factors such as Organon's price relative to its total costs (marginal *and* fixed) and whether output was restricted, monopoly power cannot be found as a matter of law."). Here, there is simply no evidence of either.

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[90] Addanki Rep. Att. 8 (Ex. 53). As shown in Dr. Addanki's report, even in a narrower doxycycline oral antibiotic market, Doryx's share was only approximately [redacted] percent (based on new prescriptions for these products written by dermatologists) prior to the launch of Mylan's generic delayed-release doxycycline hyclate. Addanki Rep. Att. 10a (Ex. 53).

[91] The Third Circuit did not rely on the direct evidence method in either *Broadcom* or *Harrison Aire*, but instead resolved both using the traditional relevant market approach. *Broadcom Corp.*, 501 F.3d at 315 (holding plaintiff had properly alleged indirect effects by defining relevant market in complaint); *Harrison Aire, Inc.*, 423 F.3d at 384–85 (relying on circumstantial evidence in affirming summary judgment in favor of defendant).

[92] Plaintiffs misstate the court's decision in *Neurontin* as having "accepted a similar direct evidence analysis to that performed by Dr. Rubinfeld." Mylan Opp. at 20. But, in *Neurontin*, plaintiffs moved for partial summary judgment on defendants' alleged monopoly power. 2013 WL 4042460, at *1. The court noted that indirect evidence is more typically used to demonstrate monopoly power. *Id.* at *2. The *Neurontin* court ***denied*** the plaintiffs' motion for summary judgment on the issue of monopoly power. *Id.* at *3–4. Thus, the *Neurontin* court's decision hardly can be read as "accept[ance]" of plaintiffs' direct evidence analysis in that case.

No evidence of supracompetitive prices. Dr. Rubinfeld's "direct evidence" analysis is not nearly as "comprehensive" as Plaintiffs suggest. Mylan Opp. at 20. Dr. Rubinfeld does not consider the changes in the net price of Doryx in light of the fierce inter-brand competition Doryx faced at all times during the relevant period.[93] Dr. Rubinfeld, for example, did not even consider that Warner Chilcott introduced and modified the Doryx coupon program to compete on price with oral tetracyclines like Solodyn and generic doxycycline. *See* Section IV(A)–(B) above.

No evidence of reduced output. In addition, Plaintiffs have failed to show that Defendants' conduct reduced output. [redacted][94] As Warner Chilcott has explained, capacity and output are distinct; ***capacity*** refers to how many pills ***could be produced***, while ***output*** refers to how many pills were ***actually produced***. WC Opp. at 72. Moreover, undisputed evidence shows that upon launch of the Doryx tablets Mayne began working to ***increase*** manufacturing capacity, [redacted].[95] Mylan's Dr. Rubinfeld admits that he has not even analyzed output and instead asks this Court to

[93] *See, e.g.*, Rubinfeld Tr. 183:3–7 (Ex. 390) ("Q. Could some of it be inter-brand competition with the likes of Solodyn, which is minocycline, or Adoxa or other branded anti-acne drugs? A. It certainly could be. I haven't analyzed that here."). Dr. Rubinfeld's "comprehensive" analysis also ignores that Warner Chilcott introduced new versions of Doryx in order to keep up with brand-name competitors and remain relevant in a crowded, highly competitive tetracycline-class field. WC Mem. at 33 (discussing Doryx responses to Adoxa); WC Opp. at 47–48 (discussing Doryx responses to Adoxa and Oracea).

[94] [redacted] MA-0027245 at Slide 5 (Mylan Ex. 78) ([redacted]

[95] [redacted] (Ex. 392) ([redacted] MA-0138829 at 829–30 (Ex. 397) [redacted] MA-0674347 at 356 (Ex. 398) [redacted]). *Compare* [redacted] MA-0153187 at 189 (Ex. 431) ([redacted] MA-0564130 at 134 (Ex. 428) [redacted]

accept, without evidence or analysis, that [redacted][96]

V. Mylan's Claims Are Barred by the Four-Year Statute of Limitations

Mylan admits (Mylan Opp. at 32) that its claims accrued no later than [redacted], which even by its own theory is untimely because it is [redacted] ***before*** the July 6, 2008 start of the four-year limitations period. Neither Mylan nor the IPPs (whose complaint was served even later) can salvage their claims through attempts to invoke the continuing violation doctrine because no Plaintiff has provided the Court with any evidence to support treating the six different Doryx products as a single, continuing act.

A. Mylan Concedes that Its Claim Accrued Prior to the Limitations Period

As Defendants explained in their opening brief, Mylan's claims accrued in 2005 when Doryx transitioned to tablet form and are untimely by years under the 4-year statute of limitations. WC Mem. at 50–53. Mylan's liability and damages expert, Dr. Nelson, testified that ***all damages flow*** from the ***2005*** tablet transition. WC Mem. at 51 n.113. Nowhere is this contested in Mylan's Opposition. *See, e.g.,* Mylan Opp. at 31–33. Instead, Mylan asserts that because, absent Defendants' 2005 conduct, it would have launched generic Doryx capsules by the [redacted][97] its claims are somehow timely.[98] However, even under Mylan's theory that the harm to Mylan first became "concrete" in [redacted],[99]

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[96] Rubinfeld Rep. ¶69 n.78 (Mylan Ex. 2).

[97] Nelson Rep. ¶¶213–14 (Ex. 23) ("but for" world assumes Mylan introduces generic Doryx capsules by [redacted]; [redacted] Nelson Reb. Rep. Ex. 60 (Mylan Ex. 226) (Mylan would have received approval for generic Doryx capsule by [redacted]

[98] Mylan Opp. at 32 ("Here, absent Defendants' anti-generic strategy, ***Mylan would have expected to launch its generic Doryx capsule product in the*** [redacted]. In other words, [redacted] would have been Mylan's earliest entry date in the generic Doryx market but for Defendants' conduct, and ***thus the earliest time*** when Defendants' conduct inflicted upon ***Mylan concrete, measurable injury*** in the form of lost profits.") (emphasis added).

[99] A cause of action accrues when a defendant commits an act that injures a Plaintiff's business. In an antitrust case alleging exclusion from a market, such a claim accrues "as soon as the exclusion occurs . . . even though, in the nature of things, the victim's losses lie mostly in the future." *Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d

Mylan's claims accrued in [redacted] at the latest, ***more than*** [redacted] ***years before*** Mylan filed suit on ***July 6, 2012***. Compl., Dkt. No. 1. By Mylan's own admission, its claims are untimely.

B. Plaintiffs' Untimely Claims Cannot Be Salvaged by the Continuing Violation Doctrine

Both Mylan and the IPPs misplace reliance on the continuing violation doctrine to try to salvage their untimely filings. Mylan Opp. at 31–33; IPP Opp. at 15–16. Despite more than 100 depositions and millions of pages of discovery, neither Mylan nor the IPPs provide this Court with evidence of a single continuing violation. *Id*. Plaintiffs' own complaints identify each alleged "switch" as a separate, discrete event. *See, e.g.*, Mylan Compl. ¶52 ("Defendants' First Market Switch" in 2005); *id*. ¶¶61–62 ("Defendants' Second Market Switch" in 2008); *id*. ¶¶65-67 ("Defendants' Third Market Switch" in 2011). Plaintiffs cannot convert discrete acts separated by periods of years into a "continuing violation" merely by conjuring the label in their briefing.

Moreover, Mylan's reliance on the continuing violation label is particularly futile because the doctrine is more narrowly applied to competitors (such as Mylan) than purchasers. A competitor's cause of action accrues when the competitor is injured, not some later time when an alleged "overcharge" is paid for a particular product. *See Berkey Photo*, 603 F.2d at 295 ("[T]he business of a monopolist's rival may be injured at the time the anticompetitive conduct occurs . . . ."). Mylan admits the same. *See* Mylan Opp. at 33 ("[A] cause of action accrues when the injury first is suffered").[100] Here, despite nearly 50 pages of briefing, Mylan has not

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261, 271 (7th Cir. 1984); *Berkey Photo*, 603 F.2d 263, 295–96 (2d Cir. 1979) (competitor's claim accrues at time of anticompetitive conduct).

[100] Contrary to Mylan's assertion, the Court's March 14, 2014 Order discussing the continuing violation doctrine supports the untimeliness of Mylan's claims. The Court held that IUOE "may . . . recover only for damages caused within the limitations period." Dkt. No. 541 at 2 ¶3. Mylan, however, has not adduced any "damages ***caused*** within the limitations period." *See id.* (emphasis added). Mylan's sole damages expert, Dr. Nelson, admits as much. Nelson Tr. 251:22–252:6 (Ex. 28) (Nelson only "estimate[d] the damages associated with [the switch from capsules to tablets]" some three years outside the limitations period).

identified any injury-causing conduct after July 6, 2008 or any "injury first [] suffered" during the limitations period. As Mylan concedes (Opp. at 31–32), Mylan could avoid the bar of the statute of limitations only if Mylan was injured by an act of Defendants within the limitations period (*i.e.*, ***on July 6, 2008 or after***). *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 106 (3d Cir. 2010) (cited by Mylan) (plaintiffs can recover for damages caused by acts within the limitations period); *see also Samsung Elecs. Co. v. Panasonic Corp.*, 2014 WL 1328318, at *2 (9th Cir. Apr. 4, 2014) (cited by Mylan) (act within limitations period "must inflict new and accumulating injury on the plaintiff"). The reason is simple: none of the post-2005 "switches" caused any harm to Mylan and, therefore, cannot give rise to a continuing violation.

The only place Mylan even discusses the effect of Defendants' later changes to its product is in Mylan's statement of facts in its affirmative motion.[101] *See* Mylan Mem. at 27. Grasping at straws, Mylan merely points to Warner Chilcott's lawful petitioning of the FDA as to the scoring of the 75mg and 100mg Doryx tablets. *See* Mylan Mem. at 27. On May 1, 2009, the FDA granted Warner Chilcott's pending 2008 Citizen Petition on scoring and applesauce specifications, and the FDA ***required*** generic manufacturers, including Mylan, to meet the scoring and applesauce specifications of the branded Doryx product.[102]

[101] Mylan does not claim that its entry was delayed by Defendants' petitioning of the FDA for labeling for applesauce administration, conduct that in any event predates the limitations period (2006). Mylan Mem. at 27. Similarly, Mylan does not (and cannot) rely on Defendants' scoring change on its 150mg Doryx product to show injury. Mylan was not required to match Defendants' scoring change prior to launch. Mylan Mem. at 28. Moreover, Mylan was enjoined from launching its generic 150mg tablet prior to the disposition of the patent case, and launched on the first day the court permitted it to do so. *See Impax*, 2012 WL 1551709, at *5–6; Order of Judgment, No. 2:08-06304 (Dkt. No. 302) (D.N.J. April 30, 2012); [redacted] MYLAN-00614564 (Mylan Ex. 223).

[102] [redacted] WC2866064 at 73 (Ex. 422) [redacted]); *id.* [redacted]

But Warner Chilcott's successful petitioning of the FDA and any injury the FDA's decision caused Mylan (*e.g.*, approval and development delays) are immune from suit under the *Noerr–Pennington* doctrine. *See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 139–40 (1961) (petitioning government to influence government's action does not violate Sherman Act, regardless of party's anticompetitive intent); *see also* WC Mem. at 9–10, 59. This Court, and others, have held the *Noerr-Pennington* doctrine immunizes citizen petitions, such as Defendants' ***successful*** petition regarding applesauce labeling and scoring of Doryx. *See In re Wellbutrin XL Antitrust Litig.*, 2012 WL 1657734, at *33–34 (E.D. Pa. May 11, 2012) (granting summary judgment for Defendants where, as here, successful, non-sham citizen petition requests accounted for delay in generic approval).[103] Where it is undisputed that the FDA granted Warner Chilcott's 2008 citizen petition,[104] Mylan cannot invoke the applesauce and scoring specifications of Doryx tablets to make out a continuing violation.

VI. There Is No Genuine Dispute That the New Versions of Doryx Included Improvements over Older Versions

Whether or not Defendants' changes to Doryx "improved" the product, summary judgment for Defendants would be appropriate. Even if the Court decides that Plaintiffs have established a prima facie case under Section 2—which they have not—the Court would need to evaluate procompetitive justifications, and Defendants have adduced unrebutted evidence of the benefits of each new version of Doryx. WC Mem. at 53–57; WC Opp. at 7–9, 10–12, 15–18; *see also United States v. Microsoft*, 253 F.3d 34, 59 (D.C. Cir. 2001).

[103] *See also In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *22 (D.N.J. Sept. 5, 2013) (granting motion to dismiss because "FDA citizen petitions are generally immune from antitrust liability under the *Noerr-Pennington* doctrine" and, as here, the plaintiffs had not established exception to the rule).

[104] [redacted] WC03356994 at 002-03 (Mylan Ex. 214).

A. There Is No Genuine Dispute that Doryx Tablets Improved the Stability of Doryx Capsules

1. The Doryx Patent Court's Finding Confirms the Stability Benefit of the Doryx Tablet

In the patent infringement case that Warner Chilcott brought against Mylan before Judge Martini, the patent court confirmed that the '161 Doryx tablet patent "***improved the dissolution stability*** of the Capsule." *Mylan*, 2012 WL 1551709, at *58 (emphasis added); *id.* at *4 ("The '161 Patent embodies [Mayne's] solution to the dissolution storage stability problem."); *see also* WC Opp. at 43–44. Mylan has no response to this finding other than to call it "dicta." Mylan Opp. at 35–36. Mylan never explains how the improved stability finding is dicta, and the patent court's opinion makes clear that the improved stability finding formed a basis for the validity ruling. As Judge Martini explained in his opinion, the "problem facing the hypothetical person of ordinary skill in the art is the 'problem of ***improving*** dissolution stability' in the Prior Art Doryx Capsule." *Mylan*, 2012 WL 1551709, at *52 (citing Mylan's post-trial brief) (emphasis added). Based on its finding that the Doryx tablet improved stability compared to the capsule, Judge Martini upheld the validity of the '161 patent against Mylan's challenge. *Id.* at *2, 51 (as part of validity ruling, "[t]he Court finds that: (a) the dissolution storage stability limitations are not rendered obvious by the prior art; (b) the stabilizing coat limitation is not rendered obvious by the prior art").

Mylan ***lost*** on the stability issue at trial and ***lost*** on the resulting validity issue, and Mylan did not challenge Judge Martini's determination that the patent protecting the Doryx tablet was valid. *See generally* Br. of Defs.-Cross Appellants Mylan Pharm. Inc. & Mylan Inc., *Warner Chilcott Co. v. Impax Labs., Inc.*, 478 F. App'x 672 (Fed. Cir. 2012) (No. 12-137), ECF No. 54 (Ex. 434). As discussed in Warner Chilcott's opposition, not only does the stability finding

confirm the benefit of the Doryx tablet, but Mylan is now collaterally estopped from claiming otherwise. *See* WC Opp. at 43–44.

2. Judge Martini's Finding Was Correct: The Doryx Tablet Improved the Stability of Doryx Capsule

Mylan's Opposition does not and cannot dispute that the patented addition of a tie coat (a thin coating around the active ingredient that helped prevent the delayed-release coating from breaking down) in the reformulated Doryx tablet improved the shelf-life stability of the product. Mylan Opp. at 34–35. Plaintiffs' formulation expert Arthur Kibbe admits that [redacted][105]

Mylan tries to downplay the Doryx capsule's stability problem and argue that it easily could have been fixed by adding a desiccant sachet. Mylan Opp. at 34–35. Plaintiffs' superficial response cannot overcome the overwhelming and undisputed evidence.

[redacted].[106] This was both a commercial risk and a quality

[105] Kibbe Tr. 41:8–12 (Ex. 145); *see also id.* 40:6–24 [redacted] *id.* 76:9–77:4 (Ex. 447) [redacted]

[106] [redacted] WC0142211 at 215 (Ex. 436) [redacted] ; [redacted] (Ex. 391) [redacted] *id.* 271:2–6 [redacted] ; Robbins Rep. ¶9 (Ex. 124) [redacted] Illum Rep. ¶¶135–69 (Ex. 114) (discussing stability concerns with Doryx capsules and improved stability of Doryx tablets); Howard Decl. ¶¶17–21, 27 (Ex. 142).

concern. In 1993, Mayne's scientists identified 74 possible causes of the Doryx capsule stability problems.[107]

Undisputed evidence also shows that, from the outset of the Doryx tablet development, Defendants sought to fix these problems and improve the stability of the product. [redacted] The ICH storage stability conditions for tablets were more stringent than those used for the Doryx capsules.[108] And it is undisputed that the Doryx capsule failed dissolution storage stability testing under the ICH conditions.[109] It is also undisputed that the Doryx tablet was approved under the ICH storage standards.[110] [redacted][111]

That both the capsule and tablet would have a 24-month shelf life is immaterial. *See* Mylan Opp. at 35. Plaintiffs cannot reasonably dispute that, when a product has a risk of losing

[107] [redacted] MAYNE-00341758 (Ex. 364) [redacted] *see also Impax*, 2012 WL 1551709, at *3 ("The list contained 74 possible causes for the instability, and focused on factors related to the delayed release coating.").

[108] Illum Rep. ¶¶149–151 (Ex.114). [redacted] *Id.* ¶151.

[109] [redacted], WC0165391 at 419 (Ex. 229) ([redacted].

[110] [redacted] WC0172943 at 946 (Ex. 438) ([redacted]).

[111] [redacted], MAYNE-00307303 at 308 (Lukas Ex. 2) (Ex. 222).

its 24-month shelf life, formulating a product that removes or reduces that risk is an improvement.[112]

It is also undisputed that the efforts to solve the stability issue through reformulation resulted in a Doryx tablet formulation that has a tighter dissolution profile than the prior Doryx capsule—*i.e.*, ***less doxycycline is released in the stomach***.[113] This means even less likelihood of nausea for the consumer.[114] The stability problems of the Doryx capsule caused a recall of both trade and sample product, a decrease in the approved shelf life from 24 to 12 months [redacted][115] While the addition of the desiccant to the packaging mitigated the exposure of the Doryx capsule to moisture, the underlying formulation issue remained.[116] [redacted].[117] Stability test results submitted to the FDA as part of Warner

[112] Illum Rep. ¶154 (Ex. 114).

[113] Illum Rep. ¶¶161–169 (Ex. 114) (explaining that the Doryx capsule could release no more than 50% of doxycycline in acid in 20 minutes while the tablet had a tighter specification allowing no more than 30% of doxycycline to release in acid in 20 minutes—which means even less likelihood of nausea for the consumer.); Appendices 22, 23.

[114] Illum Rep. ¶165, Table E (Ex. 114) ("This decrease in the amount of drug released in acid is important because it suggests that less of the drug will be released in the stomach from the 'delayed release' product and hence the potential side effects in terms of nausea, stomach-upset, or similar gastrointestinal issues should be minimized without sacrificing bioavailability."); [redacted] WC0172943 at 946 (Ex. 438) [redacted]

[115] [redacted] (Ex. 142); [redacted] WC0390775 (Ex. 351) ([redacted]; [redacted] WC0163408 at 408 (Ex. 143) ([redacted]; [redacted] WC0162413 at 413 (Ex. 200) [redacted]); [redacted] WC0066350 at 351 (Ex. 231) ([redacted], MAYNE-00161834 at 834 (Ex. 352) [redacted]

[116] Illum Rep. ¶153 (Ex. 114) ("Desiccants, however, only mitigated the Doryx capsules' stability problem; they did not resolve the inherent stability issue."); Illum Tr. 329:5–330:2 (Ex. 401) ("[M]y problem with the desiccant is that you're not really solving the problem, the underlying problem with the formulation. What you're doing is mitigating it. So, you know, the problem is still there. It's a bit like putting a finger in a dike where there's a hole. You put your finger in and the water stops, but you can't stand there forever. So the problem is still there. You haven't solved it. That's my problem with this. And you can see that even with desiccants there's still a trend of increasing dissolution in acid.").

[117] [redacted] (Ex. 432) ([redacted], Doryx-PLM-0003092

Chilcott's request to add the desiccant to the approved package showed that, even with the desiccant, the product failed stability requirements, releasing too much doxycycline in acid too quickly.[118] Moreover, with or without the desiccants that Mylan claims would fix the capsule's known stability problems (Mylan Opp. at 34), the Doryx capsule failed to meet the tightened "no more than 30% acid release" specification of the Doryx tablet over the 24 month shelf-life.[119]

Plaintiffs have no basis to argue that Defendants should have abandoned years of development and a viable tablet formulation in favor of a temporary and insufficient patch, such as a desiccant. *See, e.g.*, *ILC Peripherals*, 458 F. Supp. at 439 ("Where there is a difference of opinion as to the advantages of two alternatives which can both be defended from an engineering standpoint, the court will not allow itself to be enmeshed in a technical inquiry into the justifiability of product innovations.") (internal quotation marks omitted).

B. There Is No Genuine Dispute that Doryx Tablets Reduced the Risk of Esophageal Injury Associated with Doryx Capsules and Provided Marketing and Risk Mitigation Benefits

Plaintiffs cannot dispute that Doryx tablets reduced the risk of esophageal injuries associated with Doryx capsules. *See* WC Mem. at 55; Mylan Opp. at 40–41. Indeed, Plaintiffs and their experts did not perform any data analysis of their own to negate this benefit of Doryx tablets. Defendants' analysis showing a significant reduction in the reports of adverse esophageal events as a result of the Doryx reformulation is consistent with the medical literature and analysis of adverse esophageal events associated with other doxycycline hyclate products. Mayne Mem. at 18; WC Opp. at 10–11.

(Ex. 409) [redacted]

[118] [redacted] WC0066165 at 189 (Ex. 448) [redacted].

[119] Illum Rep. ¶¶161–169 (Ex. 114); Appendices 22, 23.

Nor can Plaintiffs reasonably dispute that the Doryx reformulation provided procompetitive marketing benefits under *Microsoft*. *See* 253 F.3d at 59 ("enhanced consumer appeal" is a benefit). Indeed, Plaintiffs' expert Dr. Kibbe admits that [redacted][120] Here, the Doryx tablet was, in part, a direct response to the marketing of a competing doxycycline product, Adoxa tablets. *See* Mayne Mem. at 19; WC Opp. at 12. By reformulating Doryx as a tablet, Defendants provided consumers with a choice between the Doryx tablet and Adoxa tablet. Plaintiffs' case theory would deprive consumers of that choice, and, therefore, actually eliminate a procompetitive benefit recognized under *Microsoft*.

Finally, Plaintiffs do not dispute that Defendants reduced liabilities and other legal risks by reformulating Doryx. *See* WC Mem. at 54; Mylan Opp. at 37–38.

C. The FDA Endorses, and Plaintiffs Admit, That Scoring Is a Benefit

The FDA, which approved the scored Doryx tablet, has issued guidelines endorsing scoring. *See* WC Mem. at 54–55. Mylan ignores the FDA's endorsement of scoring and instead attempts to obscure the value of scoring by comparing the relative prices of Defendants' Doryx products. *See* Mylan Opp. at 39–40. But Plaintiffs' approach ignores that scoring itself has value in the marketplace.[121] Even if Warner Chilcott sold scored Doryx at roughly the same price as old Doryx, consumers saved money because of the additional options made available by scoring. [redacted].[122]

[120] Kibbe Rep. ¶17 (Mylan Ex. 97).

[121] *See, e.g.*, [redacted] (Ex. 423) [redacted]).

[122] *See* [redacted] WC0373760 at 760 (Ex. 101) [redacted]

Scoring provided other undisputed benefits. Scoring can ease swallowing [redacted][123] Defendants' scoring of Doryx also negated a marketing advantage of rival Adoxa. *See Microsoft*, 253 F.3d at 59 ("enhanced consumer appeal" is a benefit); *see also* WC Mem. at 33 (Adoxa marketed "1st & ONLY Doxycycline Scored Tablet").

D. Plaintiffs Do Not Dispute that Defendants Have Developed Significant New Therapies as a Result of the Doryx Reformulations

Mylan does not dispute that Warner Chilcott has developed a new drug, sarecycline, and new therapies (*e.g.*, a new dosing regimen for chlamydia) as a result of its Doryx revenues. WC Mem. at 55–56. Mylan's observation (Mylan Opp. at 42) that the FDA has not yet approved sarecycline misapprehends the already realized benefits of Warner Chilcott's sarecycline project. Indeed, the [redacted] that Warner Chilcott has spent in research and development of sarecycline itself benefits patients. *See Eli Lilly & Co v. Premo Pharm. Labs., Inc.*, 630 F.2d 120, 137 & n.78 (3d Cir. 1980) ("[T]he development and perfection of new drugs frequently requires the devotion of years of research time and the expenditure of millions of dollars. . . . [T]his type of an investment of human and capital resources is . . . socially ***beneficial*** . . . .") (emphasis added).[124]

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[123] *See, e.g.*, [redacted] (Ex. 424) [redacted] ; (Ex. 396) [redacted] ; (Ex. 425) [redacted].

[124] *See also In re Orthopedic Bone Screw Prods. Liab. Litig.*, 1999 WL 455667, at *1 (E.D. Pa. July 2, 1999) ("The [Federal Food, Drug and Cosmetic Act] [is] intended . . . to allow the public to receive the benefits that medical research and experimentation provide . . . .").

Mylan's suggestion (Mylan Opp. at 42) that Defendants withheld discovery regarding sarecycline is false. *See* Mylan Opp. at 42. Plaintiffs did not request discovery regarding sarecycline in the first place. Plaintiffs have known about sarecycline for a long time[125]—at least since the Doryx patent litigation—and received discovery regarding sarecycline in this case. Warner Chilcott produced over ***1,500 documents*** on sarecycline, and ***3 witnesses*** ([redacted] testified about it. Yet, Plaintiffs never asked for additional discovery on this product—while they did request additional discovery on other products. Plaintiffs could have asked any of Warner Chilcott's executives about sarecycline development, but Mylan's counsel discouraged Warner Chilcott's executives from testifying on the subject.[126] Regardless, Plaintiffs' suggestion that there is nothing in the record about the benefits of sarecycline is incorrect. [redacted][127] It is a potential breakthrough drug made possible by the incremental innovation of Doryx. WC Mem. at 56; WC Opp. at 18.

Plaintiffs' claims about Warner Chilcott's document production regarding the 200mg Doryx tablet similarly are baseless. Warner Chilcott produced over ***7,200 documents*** on the 200mg tablet approved in 2013, and ***12 witnesses*** testified about it. As with sarecycline, Plaintiffs do not and cannot dispute that the 200mg Doryx tablet's new dosing regimen for chlamydia greatly benefits patients.[128] *See LePage's, Inc. v. 3M*, 324 F.3d 141, 163 (3d Cir. 2003) (describing justifications related "to the enhancement of consumer welfare").

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[125] *See* Nelson Patent Decl. ¶44 (Ex. 395) [redacted]

[126] [redacted] (Ex. 427) [redacted]

[127] *See* [redacted] Ex. 427).

[128] *See* Kesselheim Tr. 80:15–21 (Ex. 3) [redacted] Nelson Tr. 137:13–19 (Ex. 28) [redacted]

The undisputed benefits of Warner Chilcott's sarecycline and 200mg Doryx products may explain why Plaintiffs took an ostrich approach to both products in discovery. Despite Warner Chilcott producing discovery on both sarecycline and the 200mg tablet, Plaintiffs deliberately chose not to follow up or seek more discovery on either subject. Plaintiffs' failure is another reason Plaintiffs' claims fail even under the rule of reason weighing they propose. Plaintiffs' experts never even considered the benefits of these drugs, so their proposed balancing is missing fundamental pieces, rendering their conclusions misleading and unreliable. *See, e.g.*, Nelson Tr. 140:2–5 (Ex. 421) [redacted]); Nelson Tr. 137:13–19 (Ex. 28) ([redacted].[129] [redacted] Nelson Patent Decl. ¶44 (Ex. 395) [redacted]). Yet Dr. Nelson unreasonably concludes for this case that Doryx has no procompetitive benefits without ever considering either the breakthrough sarecycline product or the innovative dosing regimen of the 200mg Doryx tablet.

VII. Miscellaneous Claims

A. The Doryx License Agreement Was Indisputably Procompetitive

The Warner Chilcott/Mayne exclusive IP license cannot be deemed a conspiracy under *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 771 (1984). [redacted]

[129] *See also* Nelson Tr. 138:8–18 (Ex. 28) ("Q. And Sarecycline, you also haven't concluded that Sarecycline's anticompetitive, correct? . . . [A.] I haven't evaluated that one. Q. And sitting here today, you can't say whether it's anticompetitive or not, correct? A. Yeah. I haven't done an analysis of Sarecycline.").

[redacted][130] [redacted] [redacted] [redacted] [redacted][131] For the entire period at issue in this case, Warner Chilcott and Mayne were never competitors in the United States. Mayne Mem. at 10. Because of Defendants' indisputable unity, Plaintiffs cannot prove concerted action to make out a Sherman Act conspiracy claim. *See Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125, 1131 (3d Cir. 1995) ("Proof of concerted action requires evidence that two or more distinct entities agreed to take action against a plaintiff.").[132]

Furthermore, undisputed evidence prevents Plaintiffs from establishing any anticompetitive or exclusionary conduct resulting from the Exclusive License Agreement. *See Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 253 (3d Cir. 2010) (Section 1 claim requires proof of "anti-competitive effects" and proof that "actions were illegal"). Seven years of tablet development led to a dramatic rise in output: Doryx sales rose from $2.5 million in 1998, when the Exclusive License was entered, to $112.1 million in 2005.[133] Joint tablet

[130] *See* Schultz Rep. ¶36 (Ex. 242); [redacted] WC0600564 at 570 (Ex. 121) [redacted], MA-0266524 at 524 (Ex. 131) [redacted]

[131] The Indirect Purchaser Plaintiffs seem to argue that any licensing agreement with exclusivity, which leads to some competitive options being limited, is illegal under the antitrust laws. *See, e.g.*, IPP Opp. at 10. However, Plaintiffs have provided no authority to support this proposition and have provided the Court with no factual evidence that the agreement between Warner Chilcott and Mayne was illegal. *See, e.g.*, IPP Opp. at 2 (stating "Defendants agreed" to perform certain acts, but citing no evidentiary support).

[132] *See also Copperweld*, 467 U.S. at 766–67 (no conspiracy liability for "unilateral behavior flowing from decisions of a single enterprise"); *Shionogi Pharma, Inc. v. Mylan, Inc.*, 2011 WL 2174499, at *5 (D. Del. May 26, 2011) (dismissing Section 1 claim by Mylan because, *inter alia*, pharma patent holder-licensor and licensee defendants were single entity incapable of conspiring under *Copperweld*).

[133] WC Opp. at 2 & Table 1; *see* WC Mem. at Appendix 6 (Nelson Rep. Ex. 8) (showing 40-fold increase in Doryx unit sales from 1997 to 2010 and 50% increase from 2005 to 2010).

development efforts have led to introduction of six new products and enhanced research and development[134]—conduct that can only be described as procompetitive. *See Copperweld*, 467 U.S. at 769 ("In the marketplace, . . . coordination may be necessary if a business enterprise is to compete effectively."); *NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 103 (1984) ("[A] joint selling arrangement may be so efficient that it will increase sellers' aggregate output and thus be procompetitive") (citation omitted).[135] Plaintiffs' conspiracy to monopolize claims fail for the same reasons. *See Carpenter Tech. Corp. v. Allegheny Techs., Inc.*, 646 F. Supp. 2d 726, 734 (E.D. Pa. 2009) (*Copperweld* is "equally applicable to Section 2 conspiracy to monopolize claims") (citation omitted).[136]

B. Plaintiffs' Attempted Monopolization Claims Fail

Plaintiffs' naked assertion that Defendants have a "dangerous probability" of "obtaining monopoly power" does not support an attempted monopolization claim. Mylan Opp. at 44. These claims fail for the same reasons Plaintiffs' monopolization claims fail. *See* WC Mem. at 57. If Plaintiffs cannot show that Defendants engaged in anticompetitive conduct, and they do not (*see* above at Section II), then their attempted monopolization claims also must fail. *See* WC Mem. at 57. Moreover, because Plaintiffs' monopolization claims fail based on Plaintiffs' inability to establish a Doryx-only product market, so too do their attempted monopolization claims. *Id.*; Mylan Opp. at 44.

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[134] *See, e.g.*, [redacted] MA-0149255 at 258 (Ex. 250).

[135] *See also Eli Lilly*, 630 F.2d at 137 & n.78 ("[T]he development and perfection of new drugs frequently requires the devotion of years of research time and the expenditure of millions of dollars. . . . [T]his type of an investment of human and capital resources is . . . socially beneficial."); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1071 (11th Cir. 2005) ("[T]he essence of research and development is the need to encourage and foster new innovations, which necessarily involves exploring licensing options and selecting which products to pursue.").

[136] *See also Dentsply*, 602 F.3d at 254–56 (dismissing Section 2 conspiracy claim where plaintiffs did not adequately allege agreement to commit "illegal" act between defendants); *see* above Section III (no causation). Warner Chilcott incorporates all arguments in Mayne's Motion for Summary Judgment and Reply in Support of its Motion for Summary Judgment on Plaintiffs' conspiracy claims.

C. Plaintiffs' Requests for Injunctive Relief Fail

Plaintiffs have abandoned their claims for injunctive relief. Mylan does not seek injunctive relief. Mylan Opp. at 45. While the IPPs initially requested injunctive relief (*see, e.g.*, IBEW Compl. at 43), that request was directed at Warner Chilcott's introduction of the 200mg Doryx tablet, which occurred in July 2013. Plaintiffs never moved for a preliminary injunction or temporary restraining order against the 200mg tablet. In fact, Warner Chilcott has moved for summary judgment as to all requests for injunctive relief (WC Mem. at 57–58), and IPPs offered no opposition whatsoever. *See* IPP Opp. (no mention of injunctive relief).

D. Mylan's Tortious Interference Claim Should Be Rejected

Mylan argues that Defendants' "intent to interfere with Mylan's business activity" by launching new products "suffices to send Mylan's tortious interference claim to the jury." Mylan Opp. at 47. But Mylan never identifies evidence establishing the elements of this claim—it should be dismissed with the antitrust claims.

Lack of Tortious Conduct (Element 1). Mylan argues that Defendants sold Doryx to third parties at "monopoly prices." Mylan Opp. at 47. But because Mylan has failed to raise a triable issue as to whether Warner Chilcott's prices could be deemed "monopoly prices" in a proper relevant market, Mylan has not and cannot identify any aspect of Defendants' conduct that was tortious.

Lack of Specific Intent (Element 2). Mylan has also presented no evidence that Defendants specifically intended to interfere with Mylan's prospective economic relations. Indeed, none of the documents that Mylan cites (Mylan Opp. at 47–48) even mention Mylan, much less any prospective business relationship of Mylan. *See* Mylan Exs. 42–44. References

to an "anti-generic strategy" are only of an intent to beat future generics with new and improved versions of Doryx. *See* WC Mem. at 60.[137]

No Damages (Element 4). Mylan asserts halfheartedly that it has "provided more than enough evidence to demonstrate damages." Mylan Opp. at 48. However, Mylan does not dispute that its proposed damages are not cognizable in tort. WC Mem. at 61; *see Gemini Physical Therapy & Rehab., Inc. v. State Farm Mut. Auto. Ins. Co.*, 40 F.3d 63, 66 (3d Cir. 1994) (not addressed by Mylan) ("[C]ausing performance of a contract to be more costly as an element of proof is too speculative and subject to abuse to provide a meaningful basis for a cause of action.") (citation omitted). As set forth in Defendants' opening summary judgment brief (at 60–61), Mylan's claim rests upon nothing more than the speculative evidence that *Gemini* rejects. *See Gemini*, 40 F.3d at 66.

Statute of Limitations. Mylan does not assert any specific reasons its tortious interference claim is timely that do not apply—but fail—with regard to Mylan's antitrust claims. Accordingly, neither the continuing violations exception, nor any other exception, saves Mylan's state-law claim from being time-barred.

E. Indirect Purchaser Plaintiffs' State Law Claims Fail

IBEW's attempt (IPP Opp. at 12–15) to adduce damages for its Florida state claim fails. In Defendants' initial brief, Defendants pointed out that IBEW cannot recover under Florida law because the challenged conduct actually increased—not decreased—the value of Doryx. WC Mem. at 61–62 (collecting cases). The cases IBEW cites support Defendants' position. In

[137] *See also Acumed LLC v. Advanced Surgical Servs., Inc.*, 561 F.3d 199, 212 (3d Cir. 2009) (not addressed by Mylan) (claim requires "purposeful action by the defendant, specifically intended . . . to prevent a prospective relation from occurring") (citation omitted); *Rossi v. Schlarbaum*, 600 F. Supp. 2d 650, 660 (E.D. Pa. 2009) (not addressed by Mylan) ("purposeful action by the defendant specifically intended to harm [plaintiff's prospective] relation"); *accord Restatement (Second) of Torts* § 766B cmt. d (1979) ("The interference with the other's prospective contractual relation is intentional if the actor desires to bring the interference about or if he knows that [the interference] is certain or substantially certain to occur as a result of his action.").

Siever v. BWGaskets, Inc., the conduct at issue so diminished the value of the product that the product was rendered ***valueless***, so the court permitted plaintiffs' to introduce a new calculation—the original purchase price of the product—to account for that diminution. 669 F. Supp. 2d 1286, 1294 (M.D. Fla. 2009).

Defendants' reading of the FDUTPA damages standard is consistent with Florida law, where the appropriate measure of actual damages is the "difference in the market value of the product . . . in the condition in which it was delivered and its market value in the condition in which it should have been delivered according to the contract of the parties." *Rollins, Inc. v. Heller*, 454 So.2d 580, 585 (Fla. Dist. Ct. App. 1984); *see also Siever*, 669 F. Supp. 2d at 1293–94 (quoting *Heller*, 454 So.2d at 585).[138] Under that standard, IBEW cannot prove any damages because Defendants' conduct caused the value of a product to increase. IBEW's brief fails to point to any court adopting any alternative damages approach.

IBEW's plea for this Court not to reexamine its FDUTPA claims underscores the claims' flaws. IPP Opp. at 14–15 (citing *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 162 (E.D. Pa. 2009); *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 537 (E.D. Pa. 2010)). In those cases, Plaintiffs alleged sham litigation and other deceptive conduct. No such allegations are present here.

Moreover, as discussed in Defendants' original memorandum (WC Mem. at 12), IPPs' state law claims fail for the same reasons their federal claims fail.[139]

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[138] *But see* IBEW Compl. ¶166 (seeking treble damages for FDUTPA claim relying upon damages standard under separate law, the Florida Antitrust Act).

[139] Indirect Purchaser Plaintiffs have provided the Court with no evidence to support their claim that Defendants have violated Nevada, California, and West Virginia laws. *See* IPP Opp. at 10–11. Plaintiffs' argument that they have "proven" *per se* violations of West Virginia and Nevada law (IPP Opp. at 10–11) is blatantly wrong because IPPs have failed to establish any illegal agreement between two or more entities, which is required under the laws of both states (as Plaintiffs' opposition concedes). IPP Opp. at 10 (stating Nev. Rev. Stat. §598A.060(1) requires Defendants "agreed" to commit certain acts); IPP Opp. at 11 n.15 (quoting W.Va. Code §47-18-5, which requires "a contract, combination or conspiracy between two or more persons"). Second, Plaintiffs provide the Court with no

CONCLUSION

For the foregoing reasons, Warner Chilcott respectfully requests that the Court grant its Motion for Summary Judgment.

Respectfully submitted this 23rd day of May, 2014.

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facts to support their arguments that they have proven Defendants violated state laws regarding monopolization (IPP Opp. at 10–11) or unfair and deceptive trade practices laws (IPP Opp. at 11).

CERTIFICATE OF SERVICE

I, Stephen Fraser, hereby certify that on May 23, 2014, I caused true and correct copies of the foregoing Defendant Warner Chilcott's Reply in Support of its Motion for Summary Judgment as to All Plaintiffs' Claims to be served by e-mail upon all counsel of record.

Dated: May 23, 2014

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